ENSURING ACCURATE SKIN TEST (PPD) RESULTS in the JURSIDICTION of the LOCAL HEALTH DEPARTMENT

GUIDELINE for ESTABLISHING or UPDATING
SKIN TESTING POLICIES, PROCEDURES, PRACTICES & EDUCATION

This guideline has been developed by the Wisconsin Department of Health and Family Services as a tool to assist local health departments in updating their policies, procedures, practices and educational programs related to tuberculin skin testing and reading. It provides a model policy and procedure, information on educational resources and additional sample resource documents for adaptation according to each local health department's needs. Items that provide additional information, education or reference are in italics or are otherwise highlighted, such as in boxes. These portions are included for use by the health department during the adaptation process, are not written in policy and procedure language and are not required for the local health department's final documents. Decisions about the application or revision of any related local health department policies, procedures, practices or educational programs are the responsibility of the local health department.

Because it is not possible for any guideline or resource to address all potential situations in practice or education, clinical judgement must always be exercised. All other legal requirements must be followed to ensure "due process" and all laws pertaining to minors and/or persons with guardians are to be followed when implementing this guideline.

When federal regulations, state statutes, administrative codes, Centers for Disease Control and Prevention (CDC) endorsed guidelines, educational programs or standards of practice pertaining to tuberculosis are revised, the Division of Public Health will notify local health departments of the availability of these resources. The Wisconsin TB Program Website, the Wisconsin Epi-Express and the Wisconsin Health Alert Network (HAN) are the official notification methods for the latest in TB information as well as for other public health issues. Local health departments need to update their policies, procedures, practices and education accordingly to remain consistent with any changes in legal requirements or tuberculosis care, for both the health of the affected individuals and the health of the public.

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GUIDELINE for PROCEDURE DEVELOPMENT

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GUIDELINE for ESTABLISHING EFFECTIVE PRACTICE	Reviewed/Revised:
ENSURING ACCURATE SKIN TEST (PPD) RESULTS in the JURSIDICTION of the LOCAL HEALTH DEPARTMENT	Signatures & Dates: _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____
_____ Health Department Original Effective Date _____ Approved by _____	

GUIDELINE for POLICY DEVELOPMENT

I. Terms and Definitions:

Clinical Evaluation – An evaluation to determine whether a patient has signs and symptoms of TB disease, how they are responding to treatment or if there are any adverse reactions to treatment. A public health nurse may perform this. (See definition for Medical Evaluation below.)

Converter – A person who has had an increase of ten millimeters or more of induration in PPD test results within a two-year period.

Extrapulmonary tuberculosis – Tuberculosis in any part of the body other than the lungs.

False Negative reaction – A reaction to a PPD skin test that fits the classification of "negative" for the person despite the presence of TB infection or disease. This may be caused by such things as anergy, over-whelming or recent infection or disease, very young (under 6 months) or advanced age, incorrect interpretation, etc. (See appendix for resource on avoiding false negative PPDs.)

False Positive reaction – A reaction to a PPD skin test that fits the classification of "positive" for the person despite the absence of TB infection or disease. This may be caused by infection with nontuberculous mycobacteria, vaccination with BCG, incorrect interpretation, etc. (See appendix for resource on avoiding false positive PPDs.)

High prevalence groups – Groups of people who are more likely to be exposed to and infected with TB, including close contacts of people with infectious TB, people born in areas of the world where tuberculosis is common, low-income groups with poor access to health care, elderly people, people who live or work in certain facilities, people who inject drugs and people in other locally identified groups.

High-risk populations – Certain demographic groups who are at a greater risk than the general U.S. public to contract a particular disease. In the case of TB, these groups include individuals who are economically disadvantaged; co-infected with HIV; persons from countries where TB is endemic; members of a racial or ethnic minority group; substance abusers; homeless persons, migrant workers; incarcerated; very young or advanced in age and those with medical risk factors for tuberculosis.

High-risk tuberculosis – An infection with tuberculosis that is highly likely to progress to active disease, may become infectious and create the potential for transmission of tuberculosis in the community if it remains untreated.

Immunocompetent – Capable of producing a normal or adequate immune response.

Immunosuppression – The suppression of natural human responses to infection as caused by disease, malnutrition, or medical treatment involving drugs or irradiation. (A person who is "immunocompromised" should be considered immunosuppressed, as the competency of the immune system is not easily measured.)

Induration – A palpable, raised, hardened area at a PPD injection site, that is measured transversely, documented in millimeters and interpreted according to the person's risk factors 48 to 72 hours after application.

Infection – The condition in which organisms capable of causing disease enter the body and elicit a response from the host's immune system. TB infection may or may not lead to active TB disease, however persons with infection remain at life-long risk of developing active disease if their infection goes untreated. Also known as latent tuberculosis infection (LTBI).

Infectious tuberculosis – Tuberculosis disease of the respiratory tract, capable of producing infection or disease in others as demonstrated most commonly by the presence of acid-fast bacilli in the sputum or bronchial secretions.

Intradermal – Within the layers of the skin.

Latent TB infection (LTBI) – Infection with *M. tuberculosis*, usually detected by a positive PPD skin test result, in a person who has no symptoms of active TB or radiographic evidence of active TB, and is not infectious. Tubercle bacilli are present in the body but the disease is not clinically active; same as TB infection.

Medical Evaluation – An evaluation, performed by a physician or a licensed physician extender, usually in response to a positive TB skin test or another reason to suspect TB, to determine a medical diagnosis. This will include a chest x-ray, unless medically contraindicated, and perhaps other tests that are medically necessary to establish a diagnosis.

Purified Protein Derivative (PPD) – A protein substance (tuberculin antigen) prepared from culture filtrates of *M. tuberculosis* that produces a delayed hypersensitivity (cellular immune) response when injected intradermally in a person whose immune system recognizes these proteins as originating from tuberculosis. *(T cells sensitized by prior TB infection come to the site and initiate a cellular reaction that results in the accumulation of fibrin deposits that create the firmness or induration. Other inflammatory cells also gather at the site, and edema and local vasodilatation can also occur.)*

Suspect tuberculosis – An illness marked by symptoms such as prolonged cough, prolonged fever, hemoptysis, weight loss, night sweats; compatible radiographic or medical imaging findings; or laboratory tests that may be indicative of tuberculosis. *Suspected tuberculosis* that is awaiting confirmation must be reported to the state and local health department.

Symptomatic – Having symptoms that *may* indicate the presence of TB *or* another disease, such as cough, fever, night sweats, weight loss, hemoptysis, etc.

TB Case – A particular episode of clinically active TB. This is only used to refer to the disease itself, not the client with the disease. By law, cases of TB must be reported to the local health department as well as suspect tuberculosis as defined above.

Tuberculin – Protein derived from tubercle bacilli that have been killed by heating that are processed and combined to make the TB skin testing antigens.

II. Purpose:

The primary purpose of this policy is to ensure that accurate results are obtained when persons who are within the jurisdiction of the health department have TB skin tests placed and read. Accurate skin test results are necessary to ensure that TB disease and infection are correctly diagnosed and is necessary to fulfill the health department's responsibility to protect the health of the public.

The policy will ensure accuracy for tests performed by health department employees by ensuring that these employees have the knowledge, skills and abilities to accurately perform and read TB skin tests. Further assurance, in addition to the provision of training, will be accomplished by carrying out the supervisory policies, procedures and practices of the agency. This will be done to ensure that employees continue to maintain their skills for the administration and reading of skin tests and are updated whenever any new CDC endorsed information is published. In addition to successful completion of training and continuing education, each employee will be trained and supervised in following the health department's policies, procedures and standards of practice regarding accurate skin testing and reading.

For TB skin tests that are placed and read within the jurisdiction of the health department by persons who are not health department employees, the health department will make every effort to also ensure the accuracy of those skin tests and readings. This will be accomplished by reaching out and developing ongoing collaboration, by offering to provide or arrange for training and by providing technical assistance in the communities and entities within their jurisdiction.

Two TB Skin Test Training Manual Programs have been developed by the National TB Centers and these programs represent the national standards of practice for education on skin testing and reading. The Francis J. Curry National Tuberculosis Center in San Francisco has a two manual set, one manual for trainers and one manual for participants. The New Jersey Medical School National Tuberculosis Center in Newark, NJ has one manual that contains all the materials for participants and is also a Train-the-Trainer course. Both of these national TB centers, along with the third one at Harlem Hospital in New York City are part of the CDC TB Control oversight system. Each of these training manuals are comprehensive and are available *free* for you to implement or adapt to your own needs. They can be ordered from the website addresses listed in the references. Skin testing education resources can also be obtained from the regional public health nurse consultant.

Training programs developed or utilized in WI should meet or exceed these national standards of practice for skin testing education.

"All TB control is local control." All TB prevention and control activities are the responsibility of the local health department. It is essential for the health department to ensure that skin testing and reading preformed within the jurisdiction of the department is done accurately and appropriately in order to maintain the standards of care for diagnosis of tuberculosis infection and disease in order to protect the health of the public. This guideline serves as an adjunct to help the local health department ensure the accuracy of TB skin test results. The health officer and health department professional staff will determine the curriculum of the training program provided or arranged for and ensure that the training meets or exceeds national standards for accurate skin testing in order to protect the health of the public.

III. Persons Affected/Responsible:

This policy will be carried out by _____ under the direction of
(List staff positions affected)
the health officer of the _____ Health Department.
City/County

IV. Suggested Policy Language:

The _____ Health Department will ensure that tuberculosis skin testing and reading by a health department employee is performed accurately by providing education and supervision to all employees placing and reading TB skin tests.

The health department will also make every effort to ensure that TB skin testing and reading performed by others within the jurisdiction of the health department is performed accurately by ongoing collaborative efforts that involve providing or arranging for education and training and by providing technical assistance.

The training curriculum developed by the Francis J. Curry National Tuberculosis Center in San Francisco and/or

_____
(Option: Specify other training curriculum in addition to, or in place of National TB Center Program)
shall serve as a model for education on skin testing and reading.

When implementing education, the health department will access the most current tuberculosis data for their jurisdiction, the state and the nation to ensure that current information is used for education and to prioritize the provision of all public health services for tuberculosis.

Emphasis and priorities for all TB services, including the provision of outreach educational programs with community partners, is based upon: first, the care of persons with suspect or active disease; second, persons who are close or high-risk contacts of persons with suspect or active disease; and third, those at risk for latent tuberculosis infection (LTBI).

All persons must have the knowledge, skills and abilities to carry out the tasks they perform. The health department may determine if unlicensed health department personnel will perform skin test application and reading. For all employees performing skin test administration or reading, both licensed and unlicensed, the health department will ensure that proper training

and supervision is carried out to ensure accurate skin test application and reading. The health department will also adhere to all applicable statutes, rules and standards of practice for training or implementation of any public health services by unlicensed staff.

The health department will also make every effort to ensure that any persons performing skin test application and reading within the jurisdiction of the health department are accurately doing so by providing ongoing collaboration with other entities and providers and offering training and updates regarding information on TB skin testing. This will also be accomplished by providing or arranging for education in the application and reading of TB skin tests to those persons and/or to those who train them.

In the event of a clinical emergency during TB skin testing, such as anaphylaxis, the health department's policies, procedures, practices and standing medical orders on clinical emergencies will be implemented immediately.

If a person who is suspected of active TB disease refuses to comply with TB skin testing and/or medical evaluation, the person may be subject to isolation or confinement pursuant to s. 252.07(8) and (9), Wis. Stats., to HFS 145 or to other and additional sanctions as the Court may determine.

In addition, a person refusing skin testing and/or a medical evaluation who is a ***contact*** to a case of active tuberculosis is subject to an order from the local health officer to submit to an examination to detect tuberculosis at the times and in the manner required by the local health officer pursuant to HFS 145.10 (12). effective April 1, 2002.

The Health Department will follow all established state statutes, administrative codes, policies, procedures and practices that are indicated for Isolation or Confinement and control of communicable disease to protect the health of the public.

V. Legal Authority:

The local health officer has authority under Wisconsin Statutes, Wis. Stats. ss. 252.07(8) & 252.07(9) and Wisconsin Administrative Code HFS 145.05 (1) and HFS 145.06 (2) through 145.06 (6), inclusive. The health officer and the health department also have the authority and responsibility that is conferred under HFS 145, Subchapter II – Tuberculosis, HFS 145.08 through HFS 145.13, inclusive, for TB control and services effective April 1, 2002.

VI. References Used for State Guideline Development

[*The following references were used to develop the model state guideline. Any additional references used by the local health department should also be listed in the final policy document.*]

1. American Thoracic Society and Centers for Disease Control and Prevention. **Diagnostic Standards and Classification of Tuberculosis in Adults and Children.** American Journal of Respiratory and Critical Care Medicine, April, 2000, 161:1376-1395.

2. American Thoracic Society. **Treatment of Tuberculosis and Tuberculosis Infection in Adults and Children** American Journal of Respiratory and Critical Care Medicine, 1994; 149: 1359-74.

3. Centers for Disease Control and Prevention. **Core Curriculum on Tuberculosis: What the Clinician Should Know**. Fourth Edition, 2000.

4. Centers for Disease Control and Prevention. **Self-Study Modules on Tuberculosis**. Modules 1-5, 1995. Modules 6-9, 2000.

5. Centers for Disease Control and Prevention. **Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection**. MMWR June 9, 2000; Vol. 49 (No. RR-6).

6. National Tuberculosis Controllers Association. **Tuberculosis Nursing: A Comprehensive Guide to Patient Care**, 1997.

7. New Jersey Medical School National Tuberculosis Center. **Tuberculosis Glossary**, 1995

8. Physician's Desk Reference (**PDR**) 56th Edition, 2002

9. Tuberculin Skin Testing for Suspected TB (DOH 7134), TB Fact Sheet found at http://www.dhfs.state.wi.us/dph_bcd/TB/Resources/TB_resources2.htm.

10. Wisconsin Department of Health and Family Services. **Wisconsin Administrative Rule, Control of Communicable Diseases**, Chapter 145.

11. Wisconsin Statues and Administrative Code Relating to the Practice of Nursing, ss. 441 Wis. Stats., **Ch. N6 - Standards of Practice for Registered Nurses/Licensed Practical Nurse**s.

12. Wisconsin Statutes, **Communicable Diseases**; ss. 252.07 – 252.10; 1999.

13. Wisconsin TB Program **Strategic Plan for Elimination of TB in Wisconsin**, 2001.

14. World Wide Web addresses, National Model TB Centers & CDC:
    Harlem Model Center – www.harlemtbcenter.org
    New Jersey Model Center – www.umdnj.edu/ntbc
    San Francisco Model Center – www.nationaltbcenter.edu
    (See appendix for complete training resource information)
    Centers for Disease Control and Prevention, CDC, Atlanta – www.cdc.gov

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GUIDELINE for PROCEDURE DEVELOPMENT

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High-risk populations – Certain demographic groups who are at a greater risk than the general U.S. public to contract a particular disease. In the case of TB, these groups include individuals who are economically disadvantaged; co-infected with HIV; persons from countries where TB is endemic; members of a racial or ethnic minority group; substance abusers; homeless persons, migrant workers; incarcerated; very young or advanced in age and those with medical risk factors for tuberculosis.

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Induration – A palpable, raised, hardened area at a PPD injection site, that is measured transversely, documented in millimeters and interpreted according to the person's risk factors 48 to 72 hours after application.

Infection – The condition in which organisms capable of causing disease enter the body and elicit a response from the host's immune system. TB infection may or may not lead to active TB disease, however persons with infection remain at life-long risk of developing active disease if their infection goes untreated. Also known as latent tuberculosis infection (LTBI).

Infectious tuberculosis – Tuberculosis disease of the respiratory tract, capable of producing infection or disease in others as demonstrated most commonly by the presence of acid-fast bacilli in the sputum or bronchial secretions.

Intradermal – Within the layers of the skin.

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Medical Evaluation – An evaluation, performed by a physician or a licensed physician extender, usually in response to a positive TB skin test or another reason to suspect TB, to determine a medical diagnosis. This will include a chest x-ray, unless medically contraindicated, and perhaps other tests that are medically necessary to establish a diagnosis.

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Symptomatic – Having symptoms that *may* indicate the presence of TB *or* another disease, such as cough, fever, night sweats, weight loss, hemoptysis, etc.

TB Case – A particular episode of clinically active TB. This is only used to refer to the disease itself, not the client with the disease. By law, cases of TB must be reported to the local health department as well as suspect tuberculosis as defined above.

Tuberculin – Protein derived from tubercle bacilli that have been killed by heating that are processed and combined to make the TB skin testing antigens.

II. Purpose:

The primary purpose of this procedure is to provide instructions that will produce accurate results when health department employees place and read TB skin tests, fulfilling the health department policy that accuracy will be ensured. This procedure is designed to focus on obtaining accurate testing application and reading *so that the results will be reliable* regardless of whether the skin testing is performed as a part of a contact investigation or for other purposes. The implementation of TB skin testing in contact or outbreak investigations should be carried out according to the guideline for contact investigations. When implementing skin testing in specific circumstances, such as for a project for early case finding in groups of persons with high incidence or prevalence of tuberculosis disease and infection, skin testing should be carried out according to the specific objectives and protocols spelled out under those project plans.

Another purpose for this procedure, and the accompanying resources, is to provide the health department with educational resources and materials to share with others in their jurisdiction who are placing and reading skin tests. Effective outreach education, collaboration and the provision of technical assistance using this procedure and these resources is necessary to enable other providers to develop and implement accurate policies, procedures and practices for placing and reading TB skin tests. Each health department will need to establish the most effective approaches in the communities that are within their jurisdiction.

III. Persons Affected/Responsible:

This policy will be carried out by _____ under the direction of
(List staff positions affected)
the health officer of the _____ Health Department.
City/County

IV. Suggested Procedure Language:

Recommendation: All care providers should be familiar with and have available for reference several of the resources on the reference list and any others that are utilized in the development of the local health department's policies, procedures and practices. The answers to most PPD questions can be obtained from these two references: "Diagnostic Standards and Classification of Tuberculosis in Adults and Children" *and* "Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection".

A. Establish an individualized agency plan for tuberculosis surveillance in the area of public health jurisdiction that addresses these public health priorities and the risks for disease and infection that are present when implementing TB skin testing programs:

1. Persons with suspect or active disease, assuring accurate, early identification.

2. Persons who are close or high risk contacts to persons with active disease, utilizing the agency's policies, procedures and practices for Contact Investigation, and/or the guideline *"Conducting Comprehensive Contact & Source Case Investigations"*.

   a) Advance to testing contacts that are not close or high-risk contacts if indicated by analysis of first round skin testing results as per contact investigation protocols.

   b) Advance any contact with signs or symptoms of active disease or who otherwise meets the definition of a suspect immediately to suspect status, equal with the persons listed above in number one.

   c) Begin a new contact investigation for the individual with confirmed active disease.

3. Persons who are at risk for active tuberculosis disease or TB infection because of medical risk factors (especially the person who is HIV +) or population risk factors (such as from a country where TB is endemic) but are not persons identified in the above (#1. or #2.).

4. Provide or arrange for the necessary education regarding the correct application and reading of PPD skin tests. The first priority is health department employee accuracy, then education and technical assistance to providers of skin testing outside the agency, as indicated, to ensure protection for the health of the public.

5. Perform other skin testing activities if resources allow these activities without interference with the primary function of protecting the health of the public, such as those needed for building or sustaining community partner relationships.

Utilization of agency resources is a local issue. Decisions and priorities are based upon the primary focus of protecting the health of the public. For instance, when the incidence of active TB disease is low in the health department's area of jurisdiction, providing PPDs and follow-up treatment to persons with high-risk medical issues, ***especially those who are HIV positive****, may decrease the overall burden on agency resources for treatment of active disease. Each person who is HIV +* ***should*** *receive a PPD and be evaluated for TB disease or infection and each active TB disease case* ***should*** *receive an HIV test along with appropriate follow up. Persons with an LTBI diagnosis benefit greatly from early determination of HIV status due to their increased chance of breaking down with active disease. Confidential coordination in the local health department is essential to meet the needs of all the clients and to protect the health of the public.*

Another example: if there are persons in the health department's jurisdiction who are applying or reading skin tests incorrectly, the greater benefit may be obtained by providing ongoing education and technical assistance, rather than using health department resources to follow up on incorrect results. The WI TB Program can assist with this analysis and education upon request.

Skin testing requires follow up. A commitment to testing a person implies a commitment to provide, arrange for, and follow through on their diagnostic work-up and for the completion of a full, CDC approved treatment regimen when TB disease or infection is identified.

A decision to test is a decision to treat correctly, and to treat completely. Incomplete treatment may create a risk to the health of the public.

B. Physician's Medical Orders and Agency Protocols for Emergency Care

1. Follow health department policies, procedures and practices regarding physician's orders for the application of PPDs or secure "Standing Physician's Orders" according to policy. [*Refer to appendix resource for sample physician's orders*.]

2. Obtain individual physician's orders for the administration of any emergency epinephrine you intend to administer to a person or secure "Standing Physician's Orders" according to health department policies, procedures and practices for emergency care.

3. Follow agency policies, procedures and practices for emergency care and ensure that persons who administer PPDs are educated/competent in carrying out any emergency protocols of the agency. *(For instance, an agency may choose to have available for administration epinephrine 1:1000 in the rare case of a severe allergic reaction. If this is the determination, physician's orders are indicated and personnel need to be competent in carrying out this protocol.)*

C. Selection, storage and utilization of products for PPD administration

[*Refer to appendix resources entitled "Resources for PPD Antigens – March 2002" and "Storage and Handling of Tuberculin Skin Testing Antigen (PPD)"*]

1. Select PPD antigens for Mantoux TB skin testing that best meet the needs of the clients of the agency for TB skin testing recognizing these key points:

a) The four-pronged TB skin test ("Tine test") is not considered accurate for TB surveillance/containment efforts and should not be used in public health

b) Large studies have proven that there are no statistically significant differences in the two antigens for Mantoux testing produced and supplied in the United States, Tubersol and Aplisol. [However there are individual differences in response to antigens to consider when selecting an antigen. Also refer to later sections of this procedure on two-step testing, considerations listed in sections below that describe possible reasons to reapply a skin test, and appendix resource on avoiding false negative and false positive results.]

Note: Refer to current product insert, manufacturer's instructions or current Physician's Desk Reference (PDR) or a similar recent clinical reference as a standard of practice. Check for any new information published after development of this guideline when administering any medication or biological product.

c) Individuals may react differently to PPD preparations (Tubersol or Aplisol) and the other products that are contained in them, such as stabilizers, preservatives, etc.

d) Individuals may also react differently to different lot numbers of the same antigen, and there may be cross-reactions to other non-tuberculous mycobacteria (such as those found in soil and water) that the body has had in the past or still has. The immune system can be "confused" by bacteria that it "thinks" might be TB. This can occur with either antigen.

e) Evaluate whether to re-apply the PPD with the other PPD preparation or a different lot number if you get a PPD response that is not what you expect for the person's risk factors. Before re-applying a PPD, determine that the previous "reaction" was not severe enough to be judged as a contraindication for reapplication. (For example, a Wisconsin born person who has never left the state, has no medical or population risk factors and has had a pre-employment PPD with a questionable result.)

f) Consider the following as adverse reactions that would contradict re-application of a PPD, regardless of the antigen selected:

- Vesiculation
- Ulceration
- Necrosis
- Severe allergic reaction

(*A minor occurrence of redness and/or itchiness that occurs in the first 24 to 48 hours after application and resolves should not be confused with induration and may not necessarily be considered a severe allergic reaction; assess the reaction or the description of the reaction and make a clinical judgement with the client's participation. A person may refuse a skin test under ordinary circumstances when there is not a risk to the health of the public as it is an invasive procedure. See sections E., G., and H. of procedure and appendix resources.)*

2. Storage and usage of selected antigen(s). [*See appendix resource entitled "Storage and Handling of Tuberculin Skin testing Antigen (PPD)*.]

   a) Check manufacturer's expiration date on bottle before using. *(This date is the "shelf life" date; the date given to a product by the manufacturer for an unopened vial. If the product has been handled and stored correctly, an unopened vial that does not exceed this date should be safe to administer if inspection reveals no concerns.)*

   b) Visually inspect product before each use for particulate matter and discoloration and discard if either is seen.

   c) Date and initial the bottle when the vial is opened.

   d) Discard 30 days after opening to avoid possible oxidation and degradation, which may affect potency.

   e) Avoid transferring PPD solution from one vial to another.

   f) Avoid exposure to strong light; PPD is sensitive to light. Store vials in darkness except when product is being drawn up. Do not pre-draw multiple syringes.

   g) Administer skin tests as soon after the syringe has been filled as possible. [A safe time frame is *not* established. See Section VI, part A of the Diagnostic Standards and Classification of Tuberculosis in Adults and Children, #1. on reference list.]

   h) Store at 35 to 46 degrees Fahrenheit in a refrigerator or a cooler with ice packs when taken out of refrigerator. Do not freeze.

   i) Ensure proper refrigerator function and do not use refrigerator door for storage.

D. Infection Control and Safety Precautions

1. Ensure that all staff who perform TB skin testing are competent and prepared to safely perform TB skin testing and that effective agency policies, procedures and practices are in place to address at least the following:

   a) Blood borne pathogen protections.

   b) Infection control precautions, including correct implementation of respiratory precautions, isolation and/or confinement.

   c) Availability and implementation of equipment to ensure safe use and disposal of sharps and medical waste.

   d) Selection and correct use of personal protective equipment (PPE), including respiratory protection when indicated.

e) Proper exposure response plan in case of an accidental needle stick and in case of accidental exposure to active tuberculosis disease.

2. Perform appropriate hand washing according to the principles of infection control and the policies, procedures and practices of the health department prior to the application of PPDs.

3. Wear gloves according to agency policy, supervisor's direction or when judged to be necessary under the circumstances presented by the individual or the testing environment.

4. Dispose of any biological waste properly if necessary. [Under normal circumstances, very little, or no blood at all is produced when performing a PPD and ordinary trash handling is adequate.]

5. Use safe needle products, safe needle handling and safe sharps containers per agency policy, procedure or practice, avoiding accidental needle sticks, including when skin tests are placed in the client's home.

6. Prepare in advance for response to accidental sharps injury and for accidental exposure to active TB according to agency plan. [Refer to agency's plan for OSHA Blood Borne Pathogen Employee Protections for complete employee protection plan.]

7. Ensure that personnel who place PPDs remain current with immunizations appropriate for persons utilizing needles in their practice and correct any deficient areas that are identified.

E. Evaluate the person who is to receive the PPD and prepare them prior to placement

1. Comprehensively assess the person for at least the following regarding the placement of the PPD: [*See appendix for sample assessment form or use your own assessment documentation and intake process*.]

   a) Assess the person's need/reason for PPD and proceed according to the priorities of the agency plan and your judgement. [First - suspect and active disease case finding, close contact testing, contact investigation expansion if indicated, then targeted testing/screening for disease and infection in high risk medical/population risk factor groups, then administrative testing if priorities are satisfied and resources available.]

   b) Reevaluate the person if you are uncertain about how they "fit" into the agency priorities and protocols for skin testing. Use the following key points to guide your judgement:

      - An infant under six months may not have a response to a PPD due to an immature immune system, but **if they are a close contact** to an active pulmonary disease case, **place a test**. In many cases re-testing after age six

months may be indicated.

- A person who is immunosuppressed (or "immunocompromised") may not have a response or the response may be weak, but **if they are a close contact to a case, a PPD is indicated**, regardless of immune status.

- Use accurate cut points for the risk factors (such as 5mm for an immunosuppressed person), and do not hesitate to apply a PPD that is needed based on the possibility that you might not get a "true" response.

- Educate physicians and nurses not familiar with the year 2000 cut point criteria and persons who have been told in the past that they are "positive" about the facts on skin testing and the importance of skin testing a person when it is indicated. Correct myths when given opportunities.

- Seek supervisory input or assistance from others, including the Wisconsin TB Program for judgements about skin test issues when the results are unclear.

c) Assess the person who refuses a PPD, saying they are "positive" but they have no documentation of this result, asking to them to describe the details of their testing and reaction. Use the following key points to guide your clinical judgement:

- Consider applying a skin test if they have no recall of the induration and they have no description of vesiculation, ulceration, necrosis, or a severe allergic reaction that you judge as a contraindication to placing another PPD. (To help with your clinical judgement regarding what is minor versus severe see below.*****)

- Vesiculation, ulceration, necrosis or severe allergic reaction are all contraindications for reapplication of a skin test.

- *****A minor occurrence of redness and/or itchiness that occurs in the first 24 to 48 hours after application and resolves should not be confused with induration or with a severe allergic reaction.

- A person can decline receiving a PPD under ordinary circumstances if they do not represent a risk to the health of the public as it is classified as an invasive procedure.

d) Evaluate the potential for contact with a person with active disease since any prior PPD and also ask the person to describe any past reactions

e) Determine reapplication on a case by case basis based upon a comprehensive assessment of the person's risk factors, exposure/travel history and the reliability and documentation of previous test results. [*See appendix resource entitled "Avoid These Factors To Help Prevent False Negative & False Positive Tuberculin Skin Tests (PPDs)"*]

The CDC may issue further guidance/recommendations regarding the concept "when in doubt, repeat the test." If this occurs, the WI TB Program will alert public health departments through updated information on the WI TB Program Website.

2. Evaluate for signs, symptoms and duration of symptoms for active TB disease and other pertinent history. [*See sample assessment in appendix or utilize your own.*]

   a) Assess comprehensively for clinical signs, symptoms and duration.

   - Cough, characteristics and duration
   - Fever, when, how high, and for how long
   - Hemoptysis, description and duration
   - Night sweats, description and duration
   - Unintentional weight loss, amount, duration
   - Loss of appetite, description and duration

   b) Assess for history of "exposure" to active TB disease or contact with a person with active disease. *[Use Contact Investigation policies, procedures and practices and/or Contact Investigation guideline for contacts and document with Contact Investigation documentation.]*

   c) Evaluate for all medical and population risk factors for determining "cut-point" for this person, including status of immune system if known. Consider what risk factors are highly likely if no documentation is available, or their history is unclear. *****
   [*Use sample assessment tool in appendix or your agency's tool. Check periodically for any updates/changes in cut points established by CDC. They will be published on the WI TB Program Website.*]

*****Be sure not to miss any risk factors. Consider making this determination and documenting it prior to placing the PPD as the common practice in your agency. Validate again at the time of reading and avoid accidental "reader bias." It may be better to recognize a potential risk factor at the time the person presents for the PPD, especially if they are unable or unwilling to give complete information or provide documentation to you. If a risk factor is medically eliminated later, the determination can still be made at that time that treatment is not indicated. Clear, open communication with the physician is essential to ensure the right outcome for the person at the medical evaluation level. Be certain to address all possible risk factors at the screening level and resolve any unknown or suspected risk factors when referring a person for a medical evaluation. Physicians may not be able to take the time to comprehensively assess for these risk factors or may not be aware of all that may be present for this person, if the possibility is not called to their attention. The client may not be able to advocate for themselves with the physician, particularly if there are language or cultural barriers, a person may not be willing to reveal all pertinent information, HIV status may be overlooked or unknown prior to this PPD result, and so on. **All persons with active TB disease should have HIV status established and it must be known to all direct care providers. Law binds all health care and public health staff to confidentiality standards for HIV status and all medical information.** HIV status **must** be established if the physician is considering twice weekly DOT or is thinking of prescribing once weekly Rifapentine for the continuation stage of active disease as these are not safe interventions if the person is HIV +. **Persons with LTBI**, especially those with any potential risk factors for HIV infection**, will benefit from having their HIV status established.** Knowing that critical information enables providers to treat the person with the proper protocols and helps public health and private providers to implement the proper level of vigilance for potential active disease breakdown. **HIV testing is available fee exempt from the WI State Lab of Hygiene.**

d) Use the Wisconsin TB Program Website to access the information that determines the cut points for individuals being skin tested – Criteria for Skin Test Positivity, by Risk Group. Call the Wisconsin TB Program for any questions regarding these cut points. [*See appendix for Criteria for Skin Test Positivity by Risk Group. This documents the cut points to be used throughout Wisconsin as of the year 2000. Check the TB Program Website for any further updates if research results in future cut point changes by CDC*.]

e) Determine and document the cut point to be used to evaluate the person when the skin test is to be read.

f) Evaluate history and/or documentation of

- Any previous TB skin tests/results.
- Any previous diagnosis of, or treatment for tuberculosis disease or infection.
- History of tuberculosis in the family, disease or infection, treated or untreated.
- History of immunizations, especially during past four to six weeks as vaccination with live-attenuated virus can suppress the immune response to the PPD in persons who are infected with TB.

  - Place a PPD on the same day as vaccination with a live-attenuated virus or 4-6 weeks later to avoid a false negative result from immune suppression.

  - Live-attenuated vaccines that may cause false negative PPD results are:

    1) Measles
    2) mumps
    3) rubella
    4) oral polio
    5) varicella
    6) yellow fever
    7) oral typhoid (TY21a)
    8) BCG

- History of any recent illnesses or infections – describe and evaluate. Use appendix reference document entitled "Avoid These Factors to Help Prevent False Negative & False Positive Tuberculin Skin Tests (PPDs)."

g) Evaluate pregnancy status for females. (Also refer to Section O. on Pregnancy.)

h) Evaluate for any other medical information pertinent to this person's PPD testing/TB status.

ENSURING ACCURATE SKIN TEST RESULTS in the JURSIDICTION of the LOCAL HEALTH DEPARTMENT

"There is no evidence that the tuberculin skin test has adverse effects on the pregnant mother or fetus." (MMWR, June 9, 2000)

The primary role of the health department is to discover and **treat** active disease in all persons, including pregnant women, infants and children in order for the health of the public to be protected. When there is a risk factor for active disease (such as being a close contact to a person with active disease) or there is a risk factor for the likelihood of progression from LTBI to disease (such as HIV infection), treatment of a pregnant woman is indicated to protect her health, the health of the fetus and the health of the public. TB skin testing in pregnancy can be very beneficial in high-risk groups to discover and treat active disease early, to treat LTBI before progression to active disease, and to benefit the mother and child as well as to protect the health of the public. **The final decisions about treatment lie with the woman and her physician unless there is a risk to the health of the public.** The health department should counsel and inform the mother and the physician of the recommended protocols and the appropriate care so that they can make fully informed decisions. Testing is a commitment to follow through with treatment to completion if indicated.

If a pregnant woman and/or her physician refuse PPD skin testing or medical treatment when it is indicated, this should be handled on a case-by-case basis with the involvement of qualified medical experts in both pregnancy and tuberculosis. This should also be done in consultation with the public health department as it their responsibility to protect the health of the public, including this mother and child. Risk/benefit determinations are prioritized based upon whether the diagnosis is active disease, high risk for active disease breakdown or the presence of LTBI without additional risk factors. The public health department and/or the Wisconsin TB Program can provide references for consultation with medical experts when indicated.

Employers and employees need to come to agreement on these issues by policy, procedure and practice and within adherence to OSHA standards and regulatory requirements. If skin testing is deferred for pre-employment or for periodic testing for pregnant women, reinstitution of skin testing should be ensured by employers if periodic skin testing is indicated, such as for health care workers in high-risk settings. If the pregnant woman has not been exposed to active disease, does not have medical or population risk factors and the physician does not intend to prescribe treatment while she is pregnant, skin testing may be of little value. However, a person who does not have a baseline PPD result documented within the past 12 months needs to be fully informed that there is no pre-existing baseline from which to work if she is exposed to active disease.

If a pregnant woman and/or her physician delay indicated PPD testing or delay treatment for LTBI until after the post-partum period, it is important that the public health department provides and documents education and follow up instructions. The pregnant woman and the physician need to be fully informed of the signs and symptoms of active disease, the risks and benefits of testing and treatment and the methods for contacting the health department should either change their decision about testing or treatment. The public health department remains accountable for the potential risk to the health of the public and to ensure follow up instructions and/or monitoring.

3. Providing Education and Obtaining Informed Consent

   a) Provide client with education regarding the TB skin test in a language and in a manner they fully understand and provide answers to client's questions until they are satisfied.

   b) Use interpreters for verbal instructions and dialog and/or use translated materials if the client is literate in their language and is provided with written material.

   c) Determine that the client will be able to return in 48 to 72 hours for reading, and that someone who is competent in skin test reading will be available to the client at that time. Otherwise, adjust timing or date of skin test placement.

d) Determine that the client understands the benefits and risks of the test and is willing to return to have it read. (Identify and overcome any barriers.)

e) Obtain informed consent from client and facilitate their signature on the consent form, or the signature of a parent or guardian for a minor or a ward, if applicable and document your name, signature, title and date [*Use sample in appendix or consent form of the agency if information is equivalent.*]

f) Provide for confidential handling and storage of clinical information in the health department.

g) Reassure the client and make them and their family members at ease regarding skin testing and follow up, both in the agency and for your visits to their home.

F. Application and Documentation of the PPD

1. Select a sterile tuberculin syringe with a one-quarter to one-half inch sterile 26 or 27 gauge needle for each application using safe needle precautions and ensuring safe disposal is readily available.

2. Select labeled vial of antigen from agency supply. [*See appendix resource "Storage and Handling of Tuberculin Skin Testing Antigen (PPD)"*]

3. Inspect antigen for clarity, check dates, record date & initials if you open vial, discard vial if unable to assure all criteria are met for PPD antigen as described in previous section of procedure regarding antigens. Discard any vial that has imperfections or you are not able to determine how long it has been opened. Check label. [*Right drug, right dose/strength, right person, right time/date, right route.*]

4. Cleanse vial with 70 % alcohol and allow to evaporate to avoid possibility of topical alcohol affecting the antigen.

5. Inject 0.1 ml of air into the vial, withdraw slightly more than 0.1 milliliters of 5 tuberculin units of PPD (Purified Protein Derivative) from vial just prior to administration to limit time for possible adsorption. Carefully expel any air bubbles and establish exactly 0.1 milliliters of antigen in the syringe.

6. Select inner aspect of forearm, commonly the left arm, about four inches below the elbow. Select other criteria to be used throughout agency for uniformity if desired, such as left arm, five inches below antecubital space, etc.

   a) Avoid veins, rashes, lesions or other skin irregularities.

   b) Select the scapular area of the back if unable to use inner surface of forearm due to skin problems, medical complications such as bilateral lymphedema or if client refuses use of either of the forearm sites.

7. Cleanse site using proper cleansing technique, going from inner circle to outer circle. If alcohol is used, allow alcohol to fully evaporate. Skin should be dry to avoid the possibility of topical alcohol affecting the antigen.

8. Pull skin taut and insert needle intradermally, just below the surface of the skin, bevel up is preferred for most person's skin and slide in until entire bevel opening is within the intradermal layer of the skin. If bevel is inserted down due to difficulty puncturing very tough or very thin skin, carefully rotate to bevel up position before injection.

9. Inject 0.1 ml of 5 TU intradermally, just below the surface of the skin as shown in CDC videos, slides, pictures, posters, training manuals from national TB center, etc. Avoid placing antigen subcutaneously (too deep) or too shallow (allowing some antigen to leak out) in order to ensure accurate results.

10. Withdraw needle immediately after injection, discard safely and have client continue to hold arm still. For accuracy, wheal or bleb (pale elevation of the skin) should be 6-10 mm, if measured transversely.

11. Place another PPD at once if test is assessed to **not** meet proper administration criteria, selecting a site at least several centimeters (or 2 to 2 ½ inches) away from the first dose, *clearly documenting the site chosen for the second test that is to be read*. Some persons will choose the opposite arm and a protocol may be established within the agency if desired.

12. Document the location of the PPD(s) clearly to enable the reader to be certain of the correct site to read. Avoid holding the client solely responsible for conveying this information to the reader, but keep the client fully informed of what is being done and what to expect.

13. Use a cotton ball, cotton swab or tiny gauze square, without touching the wheal, to absorb any spot of blood that may be produced around the injection site and discard safely.

    a) Avoid pressure on wheal and on injection site so as to avoid promoting any leakage of antigen.

    b) **Avoid use of Band-Aids or any type of dressing** & instruct patient and family to avoid them to prevent any possibility of affecting the skin or the test interpretation.

14. Observe client for any signs of a severe allergic response (this is very rare). Implement emergency care if needed according to agency protocol for emergency care.

15. Document at least the following for each skin test placed; provide additional documentation whenever necessary. [*See appendix for resource: "Sample TB Skin Test Consent, Documentation & Communication of Information to Physician Form".*]

    a) antigen used & lot number
    b) manufacturer's expiration date
    c) date the antigen vial was opened
    d) date and time the PPD was applied

e) client's site of injection
f) name, title, signature of person placing the skin test and date

16. Repeat documentation at the time of placement for test two when a two step test is applied [*Two step testing is addressed later in this procedure and common questions and issues are best addressed in documents # 1 (Diagnostic Standards) and # 5 (Targeted Testing) on the page of references*.]

17. Ensure that the client and family understand the following:

    a) avoiding Band-Aids or other dressings on the site
    b) leaving it alone
    c) what kind of reactions may be expected
    d) what reactions would be unexpected
    e) what should be reported to the agency
    f) what should be reported to the physician
    g) phone numbers to call for physician, if applicable
    h) phone number for agency including after hours emergency care

18. Provide them with documentation of the PPD to take with them. [See appendix for ordering free wallet cards from the State of Wisconsin that are available in English, Spanish and Hmong, or use your own agency client documentation resources.]

19. Educate client and family about importance of returning for skin test reading and give them verbal and written appointment information in a language and in a manner they understand. Recognize individual and cultural differences about keeping appointments and barriers, such as lack of transportation. Some clients will require more specific follow-up, such as a phone call reminder or a home visit.

20. Ensure follow up for return visits that are not kept using agency system for follow-up including home visits for skin test readings when needed.

21. Consider small incentives to encourage persons to return promptly for skin test readings, especially for close or high-risk contacts, or other persons who are a high-priority for identification of active disease or latent tuberculosis infection. Use of incentives *is* cost-effective if it conserves health department resource expenditure trying to follow-up unread or unplaced PPDs. *[Contact the WI TB program for any questions about use of incentives.]*

G. Accurate Reading and Documentation of the PPD (Also see Decision Trees in Appendix.)

1. Read a PPD during the 48 to 72 hour window after it was placed, measure only ***transversely***.

2. Read and classify a person's reaction as positive for ***any PPD induration*** that meets the cut point significance for their risk factors, *even if it is a result from their first PPD application and you had intended to do a second step*. Document it and refer them for a chest x-ray and medical evaluation. No further skin testing is indicated. (See Decision Trees and section H. below.)

3. Validate risk factor parameters before measuring and interpreting the PPD. When returning for readings, clients may have remembered information that was not given to the person placing the PPD. *[See appendix resource on avoiding false negative and false positive readings.]*

4. Document millimeters of induration, measured transversely (including zero millimeters when there is no reaction) and determine significance of the reaction for the individual's cut point categories.

5. Document the significance of the induration, classifying the person as positive or negative for their risk factors.

6. Provide the person with education about the meaning and significance of their result, including returning for additional skin tests if indicated. (e.g., when a two-step is indicated or if skin testing is part of a contact investigation and they need to return in 90 days, etc.)

H. Medical follow-up for a skin test that is positive for risk factors (Also see Decision Trees in Appendix.)

1. Provide or arrange for a chest x-ray and a medical evaluation for those classified as positive ensuring that the person receives a *complete* evaluation to determine the diagnosis of active disease versus latent TB infection (LTBI). (Follow Decision Tree in appendix.)

2. Ensure that ***no person*** for whom TB services are indicated is denied services for any reason, including lack of payment source or personal funds.

3. Ensure that ***each*** person with a positive PPD has a chest x-ray and a complete medical evaluation in order to rule out active disease. This ensures that the health department's role of protecting the health of the public is fulfilled.

I. Interventions for persons with reactions that are difficult to classify or persons who appear for readings outside the 48 to 72 hour window

1. Avoid a determination of "negative" significance for risk factors if the PPD was not read in the 48 to 72 hour window. **"Negative" for risk factors can only be made in the 48 to 72 hour window.**

2. Read induration that remains present up to one week after application as significantly positive if it meets the criteria of positive for risk factors for the person who appears after 72 hours.

3. Refer the person with a result that is positive for their risk factors for a chest x-ray and medical evaluation **even if they present after 72 hours**. Do not repeat the PPD.

4. Re apply a skin test when indicated by your clinical assessment using the following parameters:

   a) *Consider* repeating the skin test under the following circumstances unless the person had an adverse reaction, which means vesiculation, ulceration, necrosis or a severe allergic

reaction:

- When results are inconclusive, *or*
- When results are undocumented, *or*
- You doubt the accuracy of the previous application or reading, *or*
- You get results that are inconsistent with the clinical picture of the person, *or*
- They return for a reading beyond the 48 to 72 hour window and there is no induration, *or*
- They return for a reading beyond the 48 to 72 hour window and induration is present but it does not meet or exceed the level of significance for the persons' risk factors, *or*
- For any other clinical indications that suggest repeating the PPD may yield a more accurate assessment of the client's TB status (unless contraindicated by vesiculation, ulceration, necrosis or severe allergic reaction).

b) Document the induration and significance of a re-applied skin test using the same cut point criteria for the person's risk factors, ignoring previous results

c) Count the two applications of a repeated skin test as a "legitimate" two step test if they return one to *three* weeks after the first PPD (*documented*, not merely stated) even if they did not return to have the first one read.

d) Ignore the "missed" reading of the first application, place the second skin test and consider the reading of this **second** test as their current reading.

e) Document this second test reading as their baseline reading.

f) Reading a single PPD (such as for a health care worker undergoing serial skin testing) can be sufficient if it has been 12 months or less since the last *documented* PPD, there has been no exposure to active disease during that time, and you have no reason to suspect that the person's immune system is compromised.

g) Start over with a legitimate two step PPD process if the last reported or documented skin test result was over 12 months ago and the person will have serial testing.

5. Teach employers in the community the importance of having employees return promptly and encourage them to consider small incentives provided by the employer, such as a fruit or a dessert coupon for the lunch room, etc. [*Rationale: Accurate, current baseline skin test results by community providers diminishes problems and questions that can waste health department resources when a contact investigation includes employees that have been identified as close contacts*.]

Implementation of employment and pre-employment skin testing by private providers for adherence to regulatory and OSHA standards is primarily the responsibility of the employer. However, the health department retains the overall responsibility for TB control in the entire area of health department jurisdiction. Providing accurate and on-going education and technical assistance to employers is essential in order to conserve health department resources, ensure accurate PPD testing and screening for active disease case-finding and for identifying LTBI in the community, especially those who are at high-risk of breaking down with active disease. High-risk and high prevalence populations account for the majority of active disease cases in Wisconsin. Accurate baseline PPD results by employers are essential in order for the health department to accurately and efficiently conduct a contact investigation when an active disease case is identified. Screening of health department employees that is carried out in compliance with OSHA employment protection standards, should incorporate many of the same standards of practice that are applied to skin testing clients and should be consistent with CDC skin testing standards. Resources for employee screening are available from the national TB centers. Refer to item 16 on the reference page and the appendix for information on ordering free resources. The appendix also contains optional tools for health departments and private providers to use for analysis of skin test results.

6. Avoid "losing" people because of difficulties in skin testing follow-up, especially those who are in a high-risk or high prevalence group.

7. Consider heavily that persons may have multiple barriers to follow up, including issues such as language, culture, transportation, economics, the person's "survival" priorities and so on.

8. Re-apply the skin test if they return between 72 hours and one week, especially if some induration is noted, *and* you want to "capture" them while they are present rather than risk that they may not be able to return exactly one week later. (See section I. regarding late readings and maintain flexibility to avoid losing people.)

J. Documentation and Follow-Up

1. Document *both* the induration in millimeters *and the significance* for risk factors, classifying the person who meets or exceeds measurement for their risk factors as positive.

2. Provide or arrange for a chest x-ray and a medical evaluation for those that are positive, including follow-up to *ensure* that this occurs.

3. Provide documentation to the person tested, including those with zero millimeters of induration.

4. Instruct them in how to secure the information in the future should they lose the documentation, including agency contact information; consider language/literacy barriers.

5. Use the Wisconsin wallet card system (see ordering information in appendix) or provide the person with local health department documentation that is at least equivalent to the documentation on the wallet card and in a language that they understand.

6. Document the information in the agency record keeping system that is equivalent to at least the following*: [See appendix for resource: "Sample TB Skin Test Consent, Documentation & Communication of Information to Physician Form"].*

   a) Date and time test read.
   b) Induration in millimeters.
   c) Significance of skin test reading according to the person's risk factors.
   d) Name and title of person reading and interpreting skin test.
   e) Signature and date of signature.

7. Educate the person tested regarding what the findings mean in relation to their clinical status for tuberculosis infection and/or disease ensuring good understanding despite any language, communication or cultural barriers.

8. Ensure their participation as fully as possible and educate them about how the information is communicated *in confidence* to the medical provider of their choice when the results are significant for their risk factors.

Rationale: It may improve the person's motivation to follow through with chest x-rays and medical evaluations when they participate in the choice of their medical provider whenever possible. Understanding how public health information (their positive skin test and the need to determine absence of active disease to protect the health of the public) is transferred confidentially to medical providers may help clients to have less fear, especially if they are undocumented. ***However, written consent is not required when a health care provider needs medical or clinical information in order to be able to render assistance to the person.*** [Wis. Stats. 146.82(2)] *Health care providers continue to treat this information in a confidential manner when the health department conveys it to them. The optional lower portion of the appendix resource tool for skin test consent and documentation suggests obtaining a person's signature based upon the rationale that participating in one's health care arrangements encourages follow through with care. It is provided for selected use with individuals that you judge will benefit from this type of participation in their care. Their signature is* ***not required.***

K. The Booster Effect (Refer to Reference # 1. "Diagnostic Standards…" for description.)

1. Avoid testing the person who has a *documented* previous positive PPD or a specific contraindication (vesiculation, ulceration, necrosis or severe allergic reaction). [*See section E. entitled "Evaluating the Person Prior to Placing the PPD and Preparing them for Administration.*]

2. Recognize the booster effect versus a skin test conversion when implementing skin testing. Utilize the concepts established in CDC publications when making clinical decisions about TB skin testing, especially the "Diagnostic Standards…" (#1 in reference list and available on the TB Program Website under Provider Resources).

   a) Sensitivity to PPD may decrease or fully disappear over time.

   b) The immune system may need stimulation; a "boost" in order to "wake up and recognize" the PPD antigen.

c) Persons who have no cellular immunity to the antigens in the PPD do *not* develop a positive skin test reaction as a result of repeated skin testing. (People who have TB infection get a "boosted" reaction – it does **not** occur because of frequent skin testing if the person is **not** infected with a mycobacterium.)

3. Use a second PPD application (a two-step test) one to three weeks after the first application for the following reasons (also see section I. regarding the person who does not return for reading at the correct time).

a) For *all* persons who are going to be tested on a regular basis (such as health care workers, prison inmates, etc.) if they have no *documentation* of a negative PPD within the past 12 months. Evaluate the person for reapplication of a PPD if they state they are "positive" but do not have a *documented* past positive result and do not describe a history of an adverse reaction. [See section I. 4. a)]

b) If you have reason to believe that boosting the person's immune system will yield more accurate results (For example, an elderly person who was never tested or was possibly infected or tested many years ago or a person that you suspect may be immunosuppressed but it is not documented, and so on).

L. Skin Test Conversions

1. Identify as a **converter** a person with an increase of 10 millimeters or more over a period of two years (see "Terms and Definitions") and provide or arrange for medical follow-up as with all positive PPDs.

2. Identify persons as "converters" only when there is documentation of an initial two-step PPD **or** there are at least two *documented* skin test readings that are of negative significance within two years, the most recent one within the past 12 months.

3. Consider a person **newly infected** when their reading measures **10 millimeters or more greater than their baseline two-step PPD** (Rationale: an *increase* of 10 millimeters within a two year period meets the definition of a converter.)

4. Avoid confusing a "boosted" reaction due to an "old" or distant infection with a newly acquired infection. Establish a PPD baseline for health care workers with an initial two-step PPD to avoid boosting during future skin tests, such as when performing annual re-testing or when evaluating a new exposure to active disease. This is essential when serial testing is to be implemented.

5. Consider a person who meets the criteria for positive for their risk factors *without* any history of a recent TB exposure as a **previously infected person**. (For instance, a heath care worker had an initial baseline two step reading of 7 millimeters a year ago and this year when she is tested her reading is 10 millimeters. There has been no active TB in the area and no other employee skin test results are classified as positive. She now meets the criteria as positive for a health care worker (10 mm) but she is not a converter because the change is only 3 mm. Her immune system may have taken a long time to "wake up" from a previous infection.) Provide or arrange for a CXR and medical evaluation to rule out active disease, or facilitate active disease

treatment if that is the diagnosis, or LTBI treatment to completion if she has never been treated.

M. Anergy and suspected anergy

1. Recognize the various situations that may cause anergy when implementing skin testing utilizing the concepts established in CDC publications, especially the "Diagnostic Standards…" (#1 in reference list and available on the TB Program Website under Provider Resources)

    a) Anergy testing is not routinely recommended for use in identifying TB infection including those who are HIV infected
    b) A physician may utilize anergy testing if desired, but it is not a service that is expected to be provided by public health

2. Consider the possibility of anergy for any person with a risk factor identified on the skin testing grid, "Criteria for Tuberculin Positivity, By Risk Group" (Available on the TB Program Website, updated on a regular basis)

3. Consider *any* person with *suspected* anergy as if they are anergic even if you are unable to confirm an anergy-producing condition. Medical consultation may be helpful if the client has been receiving medical care. (For example, a person who is an IV drug user may not have a documented HIV status but they may be immunosuppressed.)

4. Test HIV + persons when testing is indicated (such as when a close contact to active disease, etc.) even if their immune system may be suppressed; recognize this factor when interpreting the results.

5. Evaluate if applying a 2nd PPD *might* produce a more accurate result although if anergy is severe a second test may still *not* produce a result (See section K. on "boosting").

6. Test infants age six months or younger if they are close contacts to a person with active TB disease but recognize that their immune system may still be immature when interpreting the results. (Infants and children who are close contacts are placed on window prophylaxis – see Contact Investigation Guideline. Retesting may be indicated after age six months if both the initial PPD and the 90 day follow up PPD were placed when the infant was under six months of age.)

N. Interpretations involving BCG

1. Avoid confusion related to previous vaccination with BCG (bacillus Calmette-Guerin) when implementing skin testing utilizing the concepts established in CDC publications, especially the "Diagnostic Standards…" (#1 in reference list and available on the TB Program Website under Provider Resources)

    a) Ignore history of BCG vaccination when interpreting skin test results.
    b) BCG is used in many parts of the world to protect from disseminated tuberculosis and TB meningitis in children, however, immunity tends to wane over time and has not been proven to protect against *pulmonary* tuberculosis for children or adults.

c) There is no reliable way to differentiate between a + PPD caused by BCG vaccination versus one due to TB infection **(***The QuantiFERON blood test for TB may help with this when it becomes more widely available*.)

2. **Interpret a PPD reaction according to the significance for the person's risk factors if they are positive, regardless of BCG status**.

3. Provide or arrange for a chest x-ray, medical evaluation and treatment to completion if the person is positive, regardless of BCG status.

4. Recognize that a positive reaction is *not* from BCG but is from *a TB infection* if the person:

   a) Is a contact to an active case.
   b) Has a large reaction (reactions from BCG tend to be small).
   c) Was vaccinated long ago (immunity tends to wane over time).
   d) Comes from an area of the world where TB is endemic.
   e) Has a history of TB disease in the family.

O. Clinical Decision-making involving Pregnancy

1. Do not consider pregnancy as a contraindication to applying a PPD *if skin testing is indicated.* Utilize the concepts established in CDC publications, especially the more recently published resource, "Targeted Testing…MMWR, June 9, 2000" (#2 in reference list and available on the TB Program Website under Provider Resources).

   a) **There is no evidence that the tuberculin skin test has adverse effects on the pregnant woman or the fetus**. [Also refer to section E., 2. h) above regarding *assessment* prior to skin testing for more information and decision-making rationale for the pregnant woman.]

   b) A person may refuse a PPD as it is classified as an invasive procedure.

   c) Active TB disease needs to be discovered and completely treated in pregnant women to protect the life of the mother and the child.

   d) A pregnant woman may receive medical advice from her physician to delay/refuse PPD screening until after the post-partum period. This may be acceptable unless there is a specific risk factor (such as being a close contact to a person with active disease or having been recently infected) or there is a risk factor for likelihood of progression from LTBI to disease (such as HIV infection). A physician and a pregnant woman may have other compelling reasons to proceed with testing and treatment, such as a desire for the timing of treatment or a need for employment. This is acceptable in the absence of medical contraindications.

   e) Treatment for LTBI is not contraindicated for the otherwise healthy woman and may be a time when she is motivated toward treatment to protect the unborn child from TB. This is especially true if her physician concurs with treatment and she receives physician and public health monitoring, as well as proper education.

f) Instruct the physician in current guidelines and treatment protocols to prevent any delay of treatment of a pregnant woman who has **HIV infection** or if she has been **recently infected**. The danger of transmission to the fetus through the placenta warrants **urgent treatment**.

g) Pregnancy alone has minimal influence on the pathogenesis of TB or the likelihood of LTBI progressing to disease, however medical and population risk factors ***do*** apply.

h) There are no studies that verify any classification changes for pregnant women; their skin test results should be classified the same as any other person, according to the established risk factor groups.

2. Follow agency or employer policy regarding the application of a PPD for the pregnant woman. Consult with the pregnant woman and her physician and document if that is the policy of your agency/institution. (See section 1. above, carefully weighing the risks and benefits.)

a) Determine prior to applying a PPD test how the results will be interpreted and used. It may be of little value to test if the physician will not prescribe treatment if the test is positive.

b) Proceed with PPD skin testing for pregnant women who are *identified* as close or high-risk contacts to active disease or *may* have been recently infected using the usual risk factor cut points.

c) Proceed with PPD skin testing for pregnant women who are identified as HIV+ or have behavioral risk factors for HIV infection using the usual risk factor cut points.

d) Notify the WI TB Program promptly if the physician or the woman refuses testing or treatment when she is a close contact to an active disease case, may have been recently infected, is HIV+, or is judged to have behavioral risk factors for HIV infection so that expert medical consultation can be secured.

A decision to test is a decision to treat, correctly and completely.

e) Apply and read PPDs that are necessary and indicated to protect the health of the pregnant woman, the fetus or the health of the public. These are common variables to consider:

- Pre-employment PPDs in pregnant women without medical or population risk factors, no history of tuberculosis or no *risk of exposure* may be delayed according to agency/institution policy.
- If the employer is subject to OSHA regulation, those standards must be followed.
- Employers must also follow the requirements of the entity that provides them with licensure, certification or accreditation and that is a variable according to the authority.
- Prior to applying the skin test, evaluate whether she will take medication or the physician will order it if the results are positive.

f) *Proceeding* with skin testing **in pregnancy for women with medical or population risk factors** is beneficial in order to discover and treat active disease early and to treat LTBI before progression to active disease

P. False-Negative and False-Positive PPD Results

1. Recognize that many factors can lead to false negative and false positive PPD results

2. Avoid situations in skin testing that can increase the chances of false results or false readings

3. Use appendix resource entitled "Avoid These Factors To Help Prevent False Negative & False Positive Tuberculin Skin Tests (PPDs)]"

V. References Used for State Guideline Development

[*The following references were used to develop the model state guideline. Any additional references used by the local health department should also be listed in the final policy document.*]

1. American Thoracic Society and Centers for Disease Control and Prevention. **Diagnostic Standards and Classification of Tuberculosis in Adults and Children.** American Journal of Respiratory and Critical Care Medicine, April, 2000, 161:1376-1395.

2. American Thoracic Society. **Treatment of Tuberculosis and Tuberculosis Infection in Adults and Children.** American Journal of Respiratory and Critical Care Medicine, 1994; 149: 1359-74.

3. Centers for Disease Control and Prevention. **Core Curriculum on Tuberculosis: What the Clinician Should Know**. Fourth Edition, 2000.

4. Centers for Disease Control and Prevention. **Self-Study Modules on Tuberculosis**. Modules 1-5, 1995. Modules 6-9, 2000.

5. Centers for Disease Control and Prevention. **Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection**. MMWR April, 2000;49 (No. RR-6).

6. National Tuberculosis Controllers Association. **Tuberculosis Nursing: A Comprehensive Guide to Client Care**, 1997.

7. New Jersey Medical School National Tuberculosis Center. **Tuberculosis Glossary**, 1995

8. Physician's Desk Reference (**PDR**) 56th Edition, 2002

9. Tuberculin Skin Testing for Suspected TB (DOH 7134), TB Fact Sheet found at http://www.dhfs.state.wi.us/dph_bcd/TB/Resources/TB_resources2.htm.

10. Wisconsin Department of Health and Family Services. **Wisconsin Administrative Rule, Control of Communicable Diseases**, Chapter 145.

11. Wisconsin Statues and Administrative Code Relating to the Practice of Nursing, ss. 441 Wis. Stats., & **Chapter N6 - Standards of Practice for Registered Nurses and Licensed Practical Nurses**.

12. Wisconsin Statutes, **Communicable Diseases**; ss. 252.07 – 252.10; 1999.

13. Wisconsin TB Program Strategic Plan for Elimination of TB in Wisconsin, 2001.

14. World Wide Web addresses, National Model TB Centers & CDC:

    Harlem Model Center – www.harlemtbcenter.org
    New Jersey Model Center – www.umdnj.edu/ntbc
    San Francisco Model Center – www.nationaltbcenter.edu
    (See appendix for complete training resource information)
    Centers for Disease Control and Prevention, CDC, Atlanta – www.cdc.gov

APPENDIX & RESOURCES

1. Ordering information for TB Skin Test Training Manuals
2. Ordering information & form for Wisconsin Tuberculosis Record – Wallet Cards
3. Ordering information & form for TB Skin Test Calipers/Rulers
4. Resource for Skin Test Reading Model Arms
5. Resources for PPD Antigens, March, 2002
6. Storage and Handling of Tuberculin Skin Testing Antigen (PPD)
7. Avoid These Factors to Help Prevent False Negative & False Positive TB Skin Tests
8. Sample Consent to Participate in TB Skin Test Training
9. Sample Medical Standing Orders
10. Sample Assessment for PPD Testing
11. Sample TB Skin Test Consent, Documentation & Release of Information to Physician Form
12. Sample TB Skin Test Refusal
13. Sample Declination of Treatment for Tuberculosis Infection
14. Optional Sample Treatment Agreement for LTBI Medications
15. Criteria for Tuberculin Positivity, by Risk Group – Wisconsin classification – [*TB Program Website will contain the most current risk classifications should any changes occur – This classification effective year 2000*.]
16. Optional Decision Trees for Skin Testing (refer to procedure for complete information, especially for contacts.)
    - "Standard" Testing
    - Two-Step Testing
17. Sample Physician Letter requesting physician orders for medical evaluation and treatment due to a positive TB skin test, significant for the person's risk factors
18. Sample Physician Letter requesting physician orders for liver function testing for persons undergoing treatment
19. TB Program Website Information – Access for latest updates, including DPH 4000 – Request for Tuberculosis Medications
20. Availability of TB Education Brochures from Minnesota
21. Skin Testing Analysis for Medical Risk Factors
22. Skin Testing Analysis for Population Risk Factors
23. Skin Testing Analysis for New Employees
24. Skin Testing Analysis for Continuing Employees
25. Sample Certificate of Participation & Sample Certificate of Completion

Ordering Information for TB Skin Test Training Manuals
Two versions are available, one from each of the two national TB centers and both are *free*.
Use these manuals as an example of educational standards in providing your PPD training.

The Web site of the Francis J. Curry National Tuberculosis Center, in San Francisco, California:

www.nationaltbcenter.edu
e-mail: **tbcenter@nationaltbcenter.edu**

Phone # (415) 502-4600

Fax # (415) 502-4620

The product that should be requested is:

Tuberculin Skin Test: A Model for Trainers

This is a **two manual set** that includes all materials needed to train both trainers and participants to place and read tuberculin skin tests. The set includes both a teacher's guide and a participant's syllabus. Slides depicting the TB skin test and a compact disk (CD) containing all the printed materials in the manuals are included. The printed materials can be adapted or copied directly from the manual or from the CD, using your own printer.

The Web site of the New Jersey Medical School National Tuberculosis Center, in Newark, New Jersey:

www.umdnj.edu/ntbcweb

Phone # (873) 972-0979
(800) 4TB-DOCS
(800) 482-3627

The product that should be requested is

Participant Manual
Tuberculosis Fundamentals and Mantoux Tuberculin Skin Testing
Train-The-Trainer Course

All material has been publicly funded and developed under the direction of the CDC and is consistent with the year 2000 changes in guidelines. It is all free, not copyrighted and can be reproduced to provide training or you may distribute it to colleagues. A copy of the manuals and the CDs from the San Francisco Center can also be borrowed from your Regional Nurse Consultant or from the WI TB Program so that you can adapt, photocopy or print the materials for your own use.

When doing skin test training you will want to begin with the most recent available TB data. Recent data is available on the WI TB Program Website and the data is updated annually. The cut points used in Wisconsin are posted on the WI TB website in the section on "Provider Resources" and is entitled "Criteria for Tuberculin Positivity, by Risk Group," and was updated in year 2000. This may be useful to any health department or for providers who use the wall chart poster from CDC on TB skin testing.

Ordering information & form for Wisconsin TB Skin Test Record -- Wallet Cards

Wisconsin Tuberculosis Record

[DOH 4756 (1/96) - Wallet Card for Skin Test Results]

Order Form

(Please print or type)

Name/Title _____

Agency _____

Address _____

_____

Phone ( ) _____ _____

Wallet cards are available in English, Spanish and Hmong. Please specify quantity needed of each:

Language Versions	English	Spanish	Hmong
Quantity Needed			

Please call the TB Program Public Health Educator at 608-267-3733 if you have any additional questions.

Mail or fax this form to:

Wisconsin Tuberculosis Program
One West Wilson St., Rm 318
P O Box 2659
Madison, WI 53701-2659

Fax: (608) 266-0049

Tuberculin Skin Test Caliper Rulers

Order Form

(Please print or type)

Name/Title _____

Agency _____

Address _____

_____

Phone ( ) _____ _____

Number of Rulers Requested _____

Please provide information on the facility and the **dates of TB skin test training** scheduled.

_____

_____

_____

Mail or fax this form to:

Nancy Dupont
Wisconsin Tuberculosis Program
One West Wilson St., Rm 318
P O Box 2659
Madison, WI 53701-2659

Fax: (608) 266-0049

Resource for Skin Test Reading Model Arms

There have been many requests for sharing information about where the TB Program obtains the life-like model arms that are used to demonstrate skin test induration.

This information is provided for your convenience and does not constitute an endorsement of any kind. Check with the company at the time of your order for current costs.
These models can be borrowed from the WI TB Program at no cost by contacting us at 608-266-9692.

HEALTH EDCO
Division of WRS Group, Ltd.
P.O. Box 21207
Waco, TX 76702-1207

Street address: 5045 Franklin Ave.

Web address: www.healthedco.com

Email: sales@wrsgroup.com

Weekdays – 8am – 6pm, Central Time

Phone Numbers:

(800) 299-3366 Ext. 295
(254) 776-6461 Ext. 295

Fax Numbers:

24 hour availability

(888) 977-7653
(254) 776-1428

Resources for PPD Antigens as of March, 2002

Tubersol ®

Aventis Pasteur, Inc.
Swiftwater, PA 18370

General Information & Customer Service
800-822-2463
507-839-7187

Adverse Drug Experiences
800-822-2463
507-839-7187

www.vaccineshoppe.com

Aplisol ®

Parkedale Pharmaceuticals
879 Parkedale Road
Rochester, MI 48307

Inquiries
888-401-2879
FAX 423-989-6279

Adverse Drug Experiences
800-546-4905
248-650-6407

www.kingpharm.com

Storage and Handling of Tuberculin Skin Testing Antigen (PPD)

1. Check expiration date on bottle before using. This date is the "shelf life" date given to a product by the manufacturer for an unopened vial. ***If*** *the product has been handled and stored correctly, an unopened vial that does not exceed this date should be safe to administer if inspection reveals no concerns.*

2. Visually inspect product before use for particulate matter and discoloration and discard if either is seen.

3. Date and initial the bottle when the vial is *opened*.

4. Discard **30 days** after opening to avoid possible oxidation and degradation, which may affect potency.

5. PPD is sensitive to light; avoid exposure to strong light. Store vials in darkness except when product is being drawn up.

6. Draw up PPD just prior to injection.*

7. Store at 35 to 46 degrees F^o in a refrigerator or a cooler with ice packs. Avoid freezing. Avoid using refrigerator door for storage.**

> *Note: As a standard of practice, refer to current product insert, manufacturer's instructions or current Physician's Desk Reference (PDR) to check for any* ***updated*** *information when administering a medication or biological product.*

* "PPD, when diluted in a buffered diluent, is adsorbed in varying amounts by glass and plastics…To minimize reduction in potency by adsorption, tuberculin should never be transferred from one container to another, and skin tests should be given as soon after the syringe has been filled as possible." [*Reference: Diagnostic Standards and Classification of Tuberculosis in Adults and Children, Am. Journal of Resp. Care Med., October, 1999, Vol. 161., page1388.*]

To avoid any possibility of PPD adsorption onto the interior of the syringe, (partially controlled by the addition of the stabilizer Tween 80 to the PPD solution) draw up the PPD just prior to administration. This is a standard recommendation from CDC references and TB research has not firmly established any particular "safe" time frame.

Manufacturer's information for Tubersol ® indicates that "Tubersol ® will remain stable for at least four weeks when pre-filled into syringes and stored between 2 ^{o} and 8 ^{o} Centigrade (35^o to 46^o Fahrenheit). However, in order to avoid possible contamination of the product **this practice is not recommended.**" The manufacturer of Aplisol ® does not address any time frame for pre-filled syringes related to their product. Refer to manufacturer's product inserts for any updated information. [*Reference: Physician's Desk Reference (PDR) 56th Edition, 2002*]

** The local health department policy, procedure or practice for the storage of immunizations, medications requiring refrigeration or other biological products should also be in place and should have similar criteria. Guidance in this area has also been addressed in the Guideline for Effective Practice entitled Accessing Services and Resources for Persons with Tuberculosis. Refer to Section B., Receipt, Storage and Control of TB Medications in the Health Department.

Avoid These Factors To Help Prevent
False Negative & False Positive Tuberculin Skin Tests (PPDs)*

False-Negative Results can be from:

Factors related to the person being tested:

- Recent or overwhelming infection with tuberculosis **
- Presence of other infections, or severe or febrile illnesses of known or unknown causes
- Viral illnesses/conditions (e.g., measles, mumps, chicken pox, HIV)
- Bacterial illnesses (e.g., overwhelming TB,** TB pleurisy, typhoid fever, brucellosis, typhus, leprosy, pertussis)
- Fungal infections (e.g., South American blastomycosis)
- Live virus vaccinations within 4 to 6 weeks prior to PPD (e.g., measles, mumps, rubella, oral polio, varicella, yellow fever, BCG and oral typhoid) [To avoid: give PPD on the same day as the immunization or 4-6 wks. later.]
- Anergy, Immunosuppression, specific or non-specific (e.g., medications, malignancy, HIV infection)
- Metabolic conditions, such as chronic renal failure
- Low protein states such as severe protein depletion, afibrinogenemia
- Disease affecting lymphoid organs (e.g., Hodgkin's disease, lymphoma, chronic leukemia, sarcoidosis)
- Drugs (e.g., corticosteroids and many other immunosuppressive agents such as given for organ transplants)
- Age [newborns (< 6 months of age), elderly patients with "waned" sensitivity]
- Stress (e.g., surgery, burns, mental illness, graft-versus-host reactions)

Factors related to the tuberculin used

- Improper storage (exposure to light and heat)
- Improper dilutions
- Chemical denaturation
- Contamination
- Adsorption of PPD solution into the syringe (partially controlled by manufacturer's addition of Tween 80)
- Individualized false negative reactions to different lot numbers of the PPD solution (uncommon, repeat PPD if not contraindicated and confirmation of unexpected results is needed.)

Factors related to the method of administration

- Injection of too little antigen (large amount leaks out or wheal is less than six to ten millimeters)
- Subcutaneous injection (too deep)
- Delayed administration after drawing into syringe
- Injection site too close to the site of other skin tests [Recommendation is 5-6 cm (2 – 2 ½ in.) apart]

Factors related to reading the test and recording the results (These factors can also lead to **false-positive readings**.)

- Inexperienced or improperly trained reader
- Conscious or unconscious reader bias
- Error in recording or interpreting results

False-Positive Results can be from:

- Infection with other mycobacteria, especially those that are common in the environment, can produce a cross-reaction to the antigens in the PPD because the body's immune system "thinks" these mycobacteria look like tuberculosis and it makes an effort to respond. These are generally **smaller** reactions (i.e., <10 mm).
- Inexperienced or improperly trained readers
- Conscious or unconscious reader bias
- Error in recording or interpreting results (such as misinterpretation of a boosted reaction as a new infection)
- Ignore a history of BCG when interpreting results. If persons have skin test reactions who have received BCG during childhood, reactions are usually smaller than reactions caused by tuberculosis infection (i.e., <10 mm). *
- Individualized false positive reactions to different lot numbers of the PPD solution (uncommon, repeat PPD if not contraindicated and confirmation of unexpected results is needed)

* Based upon the "Diagnostic Standards and Classification of Tuberculosis in Adults and Children", a joint statement prepared by the American Thoracic Society and the Centers for Disease Control and Prevention and endorsed by the Infectious Disease Society of America in September 1999. American Journal of Respiratory and Critical Care Medicine, Volume 161 pages 1376-1395, published in year 2000. Internet: www.atsjournals.org

** The PPD skin test has a reported false-negative rate of 25% durin g the initial evaluation of persons with active tuberculosis. This appears to be due to poor nutrition and general health, overwhelming acute illness or immunosuppression and must be taken into consideration when evaluating persons who are suspected of having active disease.

Sample Consent to Participate in Tuberculin Skin Test Training

I, _____ give permission for
Name of participant receiving injection

_____ to practice intradermal
Name of participant(s) administering injection

administration of _____ for purposes of training.
Circle applicable product(s): tuberculin normal saline bacteriostatic water

Signature _____ Date _____

Sample Medical Standing Orders

(Note: This is an optional model - local health departments with effective policies/procedures/practices for standing orders may continue to use them.)

_____ Health Department
City/County

Standing Medical Order for the Administration of Mantoux Tuberculin Skin Testing

With this medical order, I hereby authorize the administration of 0.1 ml of purified protein derivative (5 Tuberculin Units) using the Mantoux Tuberculin Skin Test method to persons who are within the jurisdiction of the health department. The administration of tuberculin is part of the overall efforts of the above listed public health department to prevent and control *M. tuberculosis.*

This medical order authorizes the registered nurses employed by the above named health department to administer tuberculin. They are knowledgeable about all aspects of Mantoux Tuberculin Skin Testing and will follow the policies, procedures and practices for Mantoux Tuberculin Skin Testing set forth by the above named health department. The most current statutes, rules, CDC guidelines and standards of practice relative to this activity will be followed.

Any reactions or untoward events that occur as a result of the administration of tuberculin will be treated according to the emergency protocol established by the policies, procedures and practices of the health department and must be directly reported to me within 24 hours of occurrence. This order shall be reviewed as often as indicated, but at least on an annual basis.

Physician's Signature:

_____ Date _____

_____
Printed Name of Physician

Medical Advisor, _____ Health Department
City/County

ENSURING ACCURATE SKIN TEST RESULTS in the JURSIDICTION of the LOCAL HEALTH DEPARTMENT

SAMPLE NURSING ASSESSMENT FOR PPD TESTING *(To be completed by health dept. staff assessment below boxed area.)*
(Consent optional on this form. Consent can be obtained on other forms in health department or other appendix forms)

Name _____ A.K.A.: _____
Date of Birth _____ Current age _____ M F Race/Country of Origin _____
Address _____ Phone # _____
Physician _____ Phone # _____

1. Reason for PPD today _____
2. Have you recently been in contact with someone with active TB disease? No. If Yes, describe _____
   _____
3. Describe PPD (Mantoux) testing history (Documentation? Where? When? Why? By whom? Results?)
   _____
4. Ever receive medications or treatment for TB? Describe (infection or disease):
   _____
   Where? When? Why? By whom? _____
5. History of adverse reaction? (vesiculation, ulceration, necrosis, severe allergic reaction) or an immediate reaction (allergic-type response in first 6 to 12 hours) When? Where? Describe reaction & results:
   _____
6. Describe any recent illnesses or infections _____
7. Describe other medical conditions _____
8. Recent or current medications or treatments (cortisone, prednisone, steroids, organ transplant drugs, radiation, etc.) _____
9. Any reason you think your immunity/resistance is low? (HIV +, cancer, leukemia, diabetes, renal disease, past gastric surgery, unintentional weight loss, etc.?) Describe _____
   _____
10. Have you received any live vaccines in the *past four to six weeks*? [MMR, oral polio, varicella, yellow fever, oral typhoid (TY21a), BCG] Describe _____
    Dates &/or Documentation? _____
11. If history of BCG, describe where, when, at what age, etc. _____
12. For women – Pregnant or possibility of becoming pregnant? _____
13. Can you return in 48 to 72 hours to have the test read? _____

Please read and sign the following:

I have read, or have had explained to me in a language and a way that I understand, the information about the Mantoux Tuberculin Skin Test. I have had a chance to ask questions which were answered to my satisfaction. I agree to return in 48 to 72 hours to have the test read. I understand the benefits and risks of the test and request that the test be given to me or to the person named above for whom I am authorized to give consent.

_____ _____ _____ _____ _____
Signature *Date* *Signature of parent or guardian* *Relationship* *Date*

Sample Tuberculin Skin Test Consent, Documentation & Communication of Information to Physician Form

(Note: Information in this format is not appropriate for persons who do not speak or read English and/or have impaired literacy skills. It must be translated or interpreted and explained in a language and in a way that they understand.)

Consent to Receive Mantoux Tuberculin

I have read, or have had explained to me in a language and a way that I understand, the information about the Mantoux Tuberculin Skin Test. I have had a chance to ask questions which were answered to my satisfaction. I understand the benefits and risks of the test and request that the test be given to me.

Print Name _____ Date of Birth _____

Signature _____ Date _____

Health Department Signature _____ Date _____
(optional, not required)

Print Name _____

TUBERCULIN SKIN TEST RECORD

TEST ONE:
Manufacturer & Lot number _____ Manuf. Exp. Date _____ Date vial opened _____
Date & time test applied _____ _____ AM PM Site of injection _____
Name & title of person placing the skin test _____
Signature _____ _____
Date
Date & time test read _____ _____ AM PM **Induration _____ mm**
Significance of skin test reading according to person's risk factors _____
Name & title of person reading & interpreting skin test _____
Signature _____ _____
Date

TEST TWO IF TWO STEP TESTING PERFORMED:
Manufacturer & Lot number _____ Manuf. Exp. Date _____ Date vial opened _____
Date & time test applied _____ _____ AM PM Site of injection _____
Name & title of person placing the skin test _____
Signature _____ _____
Date
Date & time test read _____ _____ AM PM **Induration _____ mm**
Significance of skin test reading according to person's risk factors _____
Name & title of person reading & interpreting skin test _____
Signature _____ _____
Date

Client participation regarding communication of medical information to medical providers:
I understand that my Tuberculin Skin Test results and medical information will be communicated to the physician(s) with whom I will follow up. I understand that this is done to enable the physician(s) to clearly understand my condition so that I can be provided with the medical care I need if my skin test is positive.
Client Signature _____ Date _____
Printed Name _____ Date of Birth _____
Health Department Staff _____ Date _____
Printed Name _____
Referrals provided for positive skin test results: _____

Sample

(Note: Information in this format is not appropriate for persons who do not speak or read English and/or have impaired literacy skills. It must be translated or interpreted and explained in a language and in a way that they understand.)

Only to be used when there is *not* an apparent risk to the health of the public.

TB Skin Test Refusal

I have refused the administration of a tuberculin skin test. I understand that by refusing this test, there is no way to determine whether or not I am infected with the bacteria that causes tuberculosis, *Mycobacterium tuberculosis.* I understand that I may need to undergo other medical evaluations, procedures or tests, including the possibility of a chest x-ray or sputum specimens in order to determine if I have tuberculosis disease that may spread to others. I understand that if I have tuberculosis infection in my body that goes undetected or untreated, I am at risk for becoming ill with active tuberculosis disease. I understand that if I do develop active tuberculosis disease, I will put other people at risk of tuberculosis disease or infection and I will have to be in isolation/quarantine to prevent this.

I agree to notify _____ at _____of the public health
Printed Name *Phone Number*
department, my personal physician or to report to an emergency facility if I develop any signs of tuberculosis such as productive cough, chest pain, fever, chills, night sweats, coughing up blood, tiredness, loss of appetite or unintended weight loss. I also understand that if I have symptoms that are suspected or confirmed to be due to tuberculosis disease, that I will be in isolation/quarantine until I am no longer infectious.

The test and the potential effects of either having the test or refusing the test have been explained to me in a language and in a way that I understand. I have had sufficient opportunity to have my questions answered, however, I still refuse to have a tuberculin skin test.

In the future, should I change my mind and decide to have a tuberculin skin test, I will contact the public health department, my employer or my private physician to arrange to receive the test.

I understand that if my employer requires the test, they may be contacted about paying for the test.

I understand that if I have been in close, prolonged contact with someone with active tuberculosis disease or have signs or symptoms of active disease myself, I can contact the public health department to inquire if a tuberculosis skin test at no cost to me is indicated.

Client Signature: _____ Date _____

Printed Name: _____ Date of Birth _____

Health Department Signature: _____ Date _____

Printed Name: _____

Sample

Declination of Treatment for Tuberculosis Infection

(Note: Information in this format is not appropriate for persons who do not speak or read English and/or have impaired literacy skills. It must be translated or interpreted and explained in a language and in a way that they understand.)

I have been informed in a language and a way that I understand that I have a positive tuberculin skin test. This indicates that I have been infected with the bacteria that causes tuberculosis, *Mycobacterium tuberculosis.* I have been offered and refused free treatment with antituberculosis medications. I understand that I have tuberculosis infection in my body and that by refusing treatment for this infection, I am at risk for becoming ill with active tuberculosis disease. I understand that if I do develop active tuberculosis disease, I will put other people at risk of developing active tuberculosis disease or tuberculosis infection. I also understand that if I develop symptoms that are suspected or confirmed to be due to tuberculosis, that I will be in isolation or quarantined in a hospital, another institution or at home and that I will need to take several medications to treat the active tuberculosis disease.

I agree to notify _____ at _____of the public health
Printed Name *Phone Number*
department, my personal physician or an emergency medical provider if I develop any signs of tuberculosis such as productive cough, chest pain, fever, chills, night sweats, coughing up blood, tiredness, loss of appetite or weight loss.

The risks of not taking treatment for this infection, including the risk of developing active tuberculosis disease, and the risk of causing infection or disease for others if I do not take treatment, and the benefits of receiving treatment have been explained to me in a language and in a way that I understand. I have had sufficient opportunity to have my questions answered, however I still refuse to take medications for tuberculosis infection.

In the future, should I change my mind and decide to take treatment for tuberculosis infection, I will contact the public health department and/or my private physician, to arrange for re-evaluation for treatment. I understand that medications for tuberculosis infection or disease are at no cost to me.

Signature _____ Date _____

Printed Name _____ Date of Birth _____

Health Department Signature _____ Date _____

Printed Name _____

Optional Sample

[Note: Laws do *not* require a written agreement/consent form for a person to receive treatment and treatment is *not* to be with held in the absence of such agreement. **This sample is an *optional* tool designed to encourage a person's participation in their treatment, their health care arrangements and referrals and to encourage adherence. It is not intended to imply that *any* activities to protect the health of the public require a written agreement.** This approach is not appropriate for persons with language and/or literacy barriers unless carefully translated, interpreted and/or read to and understood by them. Ch. 252.03(2) specifies that local health officers may do what is reasonable and necessary for the prevention and suppression of disease;… In addition, HFS 146.82(2)(a)2. authorizes *a health care provider* access to patient health care records to the extent that performance of their duties requires it. (paraphrased)]

Treatment Agreement for Medications for Tuberculosis Infection

I, _____ _____ agree to work with _____
Name *Date of Birth* *City/County*
Health Department for medications and services to treat my tuberculosis infection. I understand that I must meet with the public health nurse on a regular basis, as scheduled in advance, to review my clinical condition and continue with my medication. If I can not keep an appointment, I will make every effort to inform the nurse in advance and I will re-schedule promptly. I understand the importance of not interrupting my treatment and if I have any difficulties remembering to take my medication, I will discuss the options with the public health nurse right away.

I have been instructed regarding my tuberculosis infection, my medication, the potential side effects to be reported and my clinical condition in a language that I understand. I have read and understand any written materials given to me and I have had an opportunity to have all my questions answered. I have been instructed and understand the signs and symptoms of active tuberculosis disease. I understand what to report and how to reach the public health nurse or what action to take in order to seek medical care if any urgent medical need develops.

I understand that I need to work with a physician and possibly other health care providers for follow-up tests, including x-rays, and sputum specimens if needed. I understand that blood samples may need to be drawn to assist the physician and the public health department with my care. I agree to provide information and to cooperate to the best of my ability. I will contact the health department if I am having any difficulty so that we can solve the problem together.

Client _____ Health Department _____ Date _____

CRITERIA FOR TUBERCULIN POSITIVITY, BY RISK GROUP

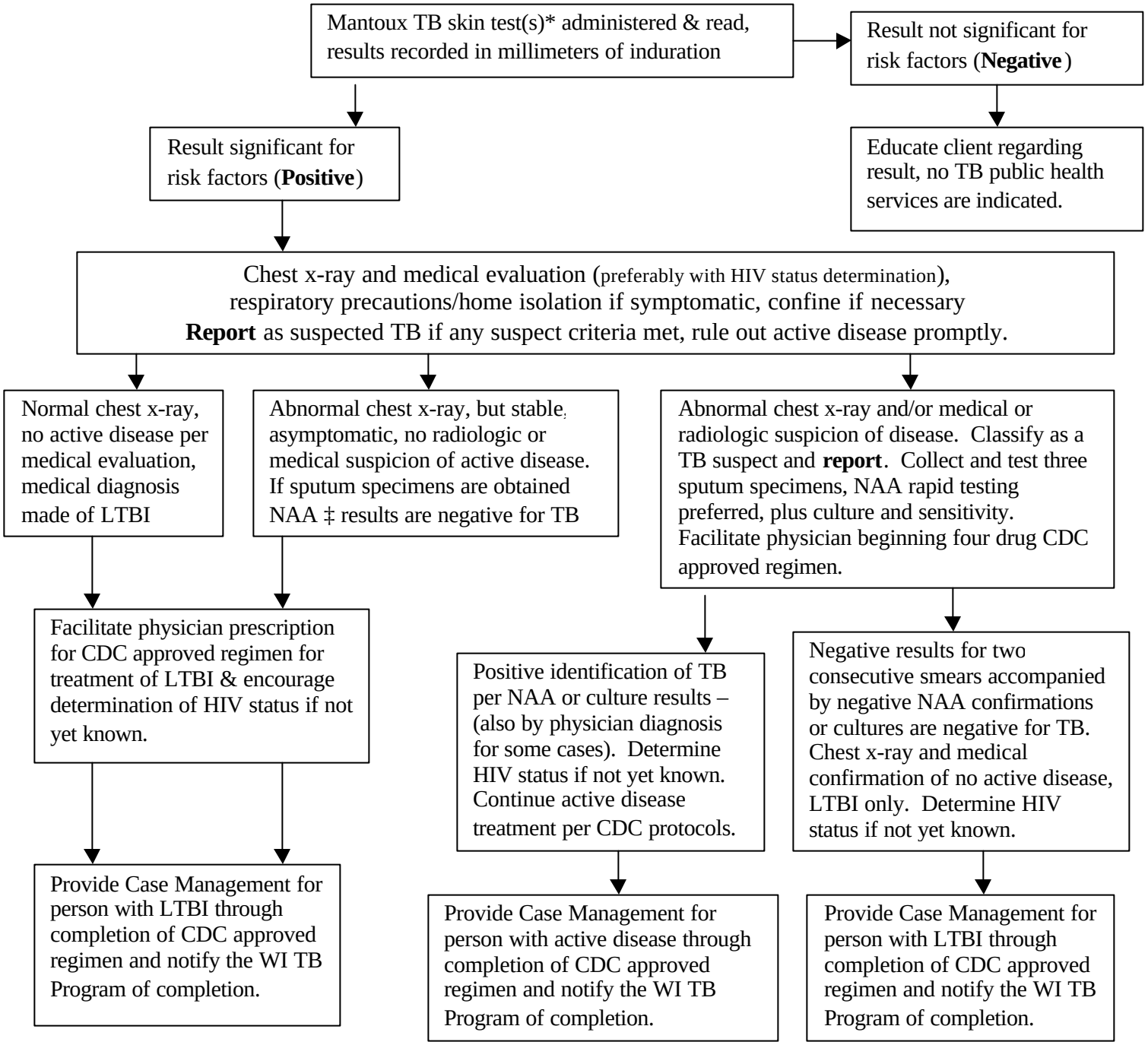
Induration ≥ 5 millimeters	Induration ≥ 10 millimeters	Induration ≥ 15 millimeters
Human immunodeficiency virus (HIV)-positive persons Recent contacts of tuberculosis (TB) case patients Fibrotic changes on chest radiograph consistent with prior TB Patients with organ transplants and other immunosuppressed patients (receiving the equivalent of ≥ 15mg/day of prednisone for 1 mo. or more*.)	Immigrants from high prevalence countries Injection drug users Residents and employees** of the following high-risk congregate settings: prisons and jails, nursing homes and other long-term facilities for the elderly, hospitals and other health care facilities, residential facilities for patients with acquired immunodeficiency syndrome (AIDS), and homeless shelters Mycobacteriology laboratory personnel Persons with the following clinical conditions that place them at high risk: silicosis, diabetes mellitus, chronic renal failure, some hematologic disorders (e.g., leukemias and lymphomas), other specific malignancies (e.g., carcinoma of the head or neck and lung), weight loss of ≥ 10% of ideal body weight, gastrectomy, and jejunoileal bypass Children younger that 4 years of age or infants, children, and adolescents exposed to adults at high-risk	Persons with no risk factors for TB

* Risk of TB in patients treated with corticosteroids increases with higher dose and longer duration.

** For persons who are otherwise at low risk and are tested at the start of employment, a reaction of ≥ 15 millimeters of induration is considered positive.

DECISION TREE – "Standard" PPD skin testing

[Refer to skin testing policy and procedure for full details; follow the **contact investigation** policy and procedure for the skin testing of **contacts** to an active TB case.]

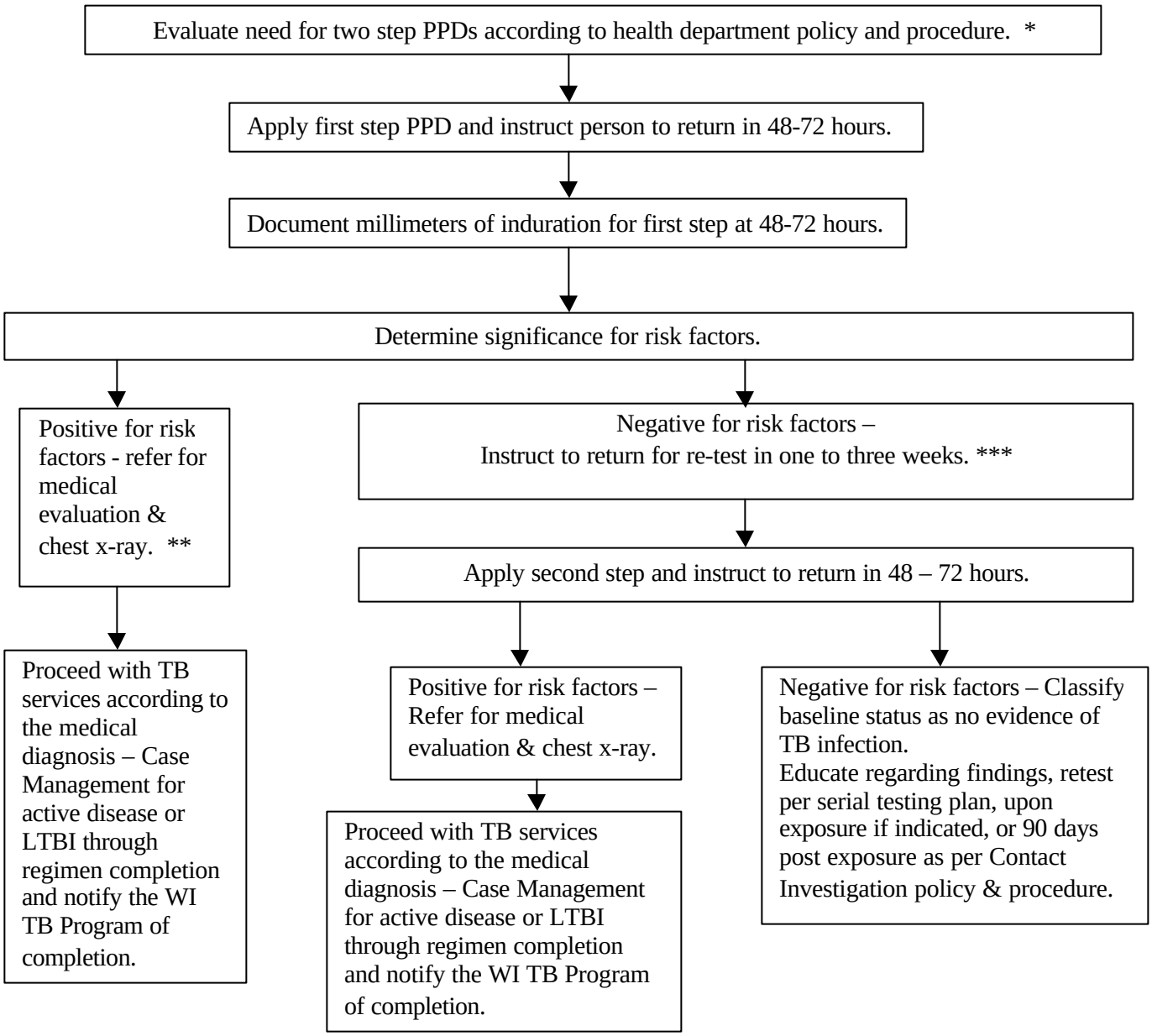


* If two step testing is indicated, use two step testing decision tree to establish result in this step before proceeding through this decision tree.

‡ Nucleic Acid Amplification testing (See Accessing Services and Resources Guideline, Section C.)

DECISION TREE – Two-step PPD skin testing

[Refer to skin testing policy and procedure for indications for two-step testing.
Follow the **contact investigation** policy and procedure for the skin testing of **contacts** to an active TB case.]



* Two-step testing is indicated if a person is expected to receive serial testing (such as health care workers, institutionalized or incarcerated persons, etc.) and may be used whenever "boosting" the immune system may lead to more reliable results.

** If a single skin test meets the criteria of positive for the person's risk factors, a second step is not needed even though they may have fit the criteria for two-step testing *prior* to the result of their first step being read as positive.

*** If a person did not appear for the reading of the first step until one to three weeks after application, reports no significant reaction and none can be palpated (positive results can remain up to one week), make a clinical judgement. Consider ignoring the missed reading of the first step and apply the second step. The second step must be read during the 48-72 hour window to be classified accurately, otherwise, reapply second step until an accurate reading is determined.

Sample Physician Letter

Requesting physician orders for medical evaluation and treatment due to a positive TB skin test, significant for the person's risk factors

Date:

Dear Dr.

This client is receiving services from our agency for a Mantoux TB skin test that is positive. Please call our agency with any questions related to this skin test result: _____ Ask for _____
Phone Number *Contact Person*

Client Name _____ Date of Birth _____

Mantoux TB Skin Test – Date Applied _____ Date Read _____ Results **(induration only)** _____mm
- ❑ Contact to a current active TB case Significance of result for risk factors _____
- ❑ Medical risk factor Specify _____
- ❑ Population risk factor Specify _____
- ❑ Chest X-ray: Date _____ Results: ÿ Normal ÿ **Abnormal *** ÿ **Abnormal but stable***

* **If abnormal, or abnormal but stable, attach chest X-ray interpretation,** if not previously submitted.

1. Please review this information, add anything additional and provide a medical evaluation to determine if the client has active TB disease or latent TB infection (LTBI). **Select the medically necessary care:**

   ÿ **Chest x-ray and interpretation** if not yet done.

2. If you determine the client has **active tuberculosis, or is a *suspect* for active tuberculosis**:

   ÿ **Report this diagnosis *or* suspect status to our agency immediately** and

   ÿ **Order treatment for active or suspect TB disease** on the Wisconsin Antituberculosis Therapy Program Initial Request for Medication, DPH 4000 (rev. 07/00). [Medications and public health visits for persons with active TB disease *or* LTBI are at no cost to the patient.]

3. If you rule out active tuberculosis, but the client has **latent tuberculosis infection (LTBI)**,

   ÿ **Complete the order for LTBI treatment on the same form, DPH 4000.**

4. If initial evaluation suggests a need for liver function testing, select the medically indicated baseline and follow up liver enzyme testing. [Reference: MMWR, Targeted TB Testing and Treatment of LTBI, 6-9-2000, Vol. 49, Page 4-5]

   ÿ AST _____ ÿ ALT _____ ÿ Bilirubin _____ ÿ Other _____ _____
   Frequency *Frequency* *Frequency* *Frequency*

It is preferred that a client ***not*** get their own prescriptions for TB medications filled. When public health is involved, they follow the client with you for public health services/monitoring, for both the person with active disease and those with LTBI. For a person with active disease, the public health nurse will obtain the medications promptly from a local pharmacy and the pharmacy will bill the Wisconsin TB program directly. For clients with LTBI, the medications are sent to the local public health department via the Wisconsin TB Program contracted pharmacy provider.

Medical and TB services that are necessary to protect the health of the public must be provided regardless of the client's ability to pay. For clients without insurance for TB services, the local public health department will provide follow up with the state TB Program to try to identify a source for reimbursement.

Physician's Signature _____ Date _____

Physician's Name _____

Sample Physician Letter
Requesting physician orders for liver function testing for persons undergoing treatment

Date:

Dear Dr.

This client is taking prescribed medications for tuberculosis and we are providing public health monitoring from our agency along with your medical care. We request that you make a medical determination and provide us with orders regarding liver enzyme monitoring. The public health department will provide or arrange for the samples to be drawn and the tests performed, fee exempt at the Wisconsin State Lab of Hygiene (WSLH) according to health department practice.

Name _____ Date of Birth _____

Please call our agency with any questions related to this client. _____ Ask for _____
Phone Number *Contact Person*

Other information if not previously known, submitted or documented may be noted here:
Mantoux TB Skin Test – Date Applied _____ Date Read _____ Results **(induration only)** _____mm
Significance of results for risk factors _____
Contact to a current active TB case. ÿ Yes, recent contact to active disease ÿ No, not a recent contact to active disease
Known Risk Factors?: _____
Chest X-ray: Date _____ Results: ÿ Normal ÿ **Abnormal *** ÿ **Abnormal but stable** *

* **If abnormal, or abnormal but stable, attach chest X-ray interpretation**, if not previously submitted.

1. To order ***baseline*** **liver enzyme monitoring***, check the tests to be drawn:

   ÿ AST ÿ ALT ÿ Bilirubin ÿ Other _____

2. To order ***follow up*** **liver enzyme monitoring***, check the tests and indicate the frequency to be drawn

   ÿ AST _____ ÿ ALT _____ ÿ Bilirubin _____ ÿ Other _____ _____
   Frequency *Frequency* *Frequency* *Frequency*

3. ÿ **No chemical monitoring is indicated***; notify me promptly of any signs or symptoms that could indicate hepatic damage. Other orders: _____

Any medical risk factor(s) identified by physician's exam? ÿ No ÿ Yes If yes, please specify:
_____

*[Reference: MMWR, Targeted TB Testing and Treatment of LTBI, 6-9-2000, Vol. 49, Page 4-5]

The medications to treat TB disease or infection are available at no cost to the client. Medical and TB Public Health services that are necessary to protect the health of the public must be provided regardless of the client's ability to pay. For clients without insurance for TB services, the local public health department will provide follow up with the state TB Program to try to identify a source for reimbursement.

Physician's Signature _____ Date _____

Physician's Name _____

Wisconsin TB Program Website Information Available for Download

When implementing TB Skin Test Education, first Check the WI TB Program Website for the most recent TB data and information and for links to statutes and administrative codes.

Phone the TB Program with any questions at

608-266-9692

www.dhfs.state.wi.us/dph_bcd/TB

Click on Provider Resources

- **DPH 4000 Form for Request for Tuberculosis Medication, revised July, 2000**
- **Criteria for Skin Test Positivity, by Risk Group revised Fall, 2000**
  (This grid is to be used throughout Wisconsin to interpret TB skin test results)
- **All Guidelines for Effective Practice related to TB are in the Provider Resources Section**

Check the WI TB Program Website for additional resources and materials in other languages.

www.dhfs.state.wi.us/dph_bcd/TB

Look in the area related to cultural competency and check for links

* * * * * * * * * * * * * * * * * *

TB Education Brochures Available for Download from Minnesota Department of Health

[Note: If you use the information from Minnesota, **be sure that you provide information on how to contact *your* health department**, such as by placing a sticker that has your health department information and phone number on it to cover the MN Division of Health information.]

www.health.state.mn.us/tb

The Minnesota Department of Health, as a result of a program funded by the Centers for Disease Control and Prevention (CDC) has produced these TB Education Brochures in nine languages:

- **Mantoux Skin Test for Tuberculosis**
- **Medicine for Tuberculosis Infection**
- **Tuberculosis Disease**
- **Medicine for Tuberculosis Disease**

The languages in which these brochures are available include:

- **Bosnian/Croatian/Serbian**
- **Cambodian**
- **Hmong**
- **Lao**
- **Russian**
- **Somali**
- **Spanish**
- **Tibetan**
- **Vietnamese**

DEPARTMENT OF HEALTH AND FAMILY SERVICES
Division of Public Health
DPH xxx (Rev. 08/02)

STATE OF WISCONSIN
Bureau of Communicable Diseases
Wis. Stats. 252.07(11)
(608) 266-9692

Sample TB Skin Test Analysis – Targeted Testing, Persons with Medical Risk Factors *

Purpose - This form should be used to determine

- The number of persons receiving a TB skin test [PPD] during this assessment period
- The number of persons with active disease or with LTBI that are identified through targeted skin testing
- The number of persons placed on medication for active TB disease or LTBI treatment
- The number of persons completing treatment for TB disease or LTBI.

Agency _____
TB Control Official _____
Assessment Period ___/___/____ to ___/___/____

Action/Finding This Assessment Period	Number	QA	Comments
Total number of persons assessed	a		Include all persons with medical risk factors assessed during this period. (Contact investigations, including those with administrative testing, are analyzed separately.)
Number of these persons with documented prior + PPD without documentation of prior LTBI treatment completion	b		Treatment for LTBI is indicated if not previously completed. Ensure a medical evaluation; expect LTBI treatment orders unless contraindicated. (Persons currently undergoing treatment are evaluated on a case-by-case basis.)
Number of these persons with documented prior + PPD who have credible evidence of completing an approved LTBI treatment regimen	c		Look for documentation of a completed regimen. (Ensure a medical evaluation when evidence is incomplete, in presence of any signs & symptoms, or for any other issues that indicate a need for a medical evaluation.)
Total persons receiving a PPD during this assessment period	d		Includes those for whom a PPD was placed, read and documented.
Number of persons identified as TB infected with newly positive PPDs	e	e ÷ d x 100 = ____%	Rate of newly identified TB infection. (Persons in c are handled on a case-by-case basis.)
Number of persons with completed medical evaluations, determined to be free of active TB disease, but with a diagnosis of LTBI	f		All untreated persons with a + PPD should be medically evaluated. (Include past positives without evidence of treatment completion for LTBI, and anyone with signs & symptoms.)
Number of persons diagnosed with active TB disease and begun on treatment	g	g ÷ a x 100 = ____%	Persons who are suspected of infectious TB disease are isolated until disease and infectiousness are ruled out. When disease is diagnosed, isolation is maintained until noninfectious and a plan for treatment adherence is established.
Number of persons completing a full, approved regimen of therapy for active TB disease as a result of this assessment effort	h	h ÷ g x 100 = ____%	Public Health priority: ensure adherence to, and completion of, a full, approved regimen for active disease treatment *unless contraindicated*, to protect the health of the public. (Also evaluate the number of persons diagnosed with active disease that complete treatment.)
Number of persons begun on LTBI treatment: (The persons in b and e with no contraindications for LTBI treatment; emphasis on high priority candidates.)	i		A person with a +PPD needs to be referred for a CXR and medical evaluation. If active TB disease is ruled out, treatment for LTBI is expected, unless contraindicated. (Also evaluate j ÷ f.)
Number of persons completing a full, approved regimen for LTBI treatment	j	j÷ i x 100 = ____%	Target efforts toward achieving completion of an approved LTBI treatment regimen unless contraindicated.

***** MMWR, June 9, 2000, Vol. 49, No. RR-6, pages 7-10.

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Sample TB Skin Test Analysis – Targeted Testing, Persons with Population Risk Factors *

Purpose - This form should be used to determine

- The number of persons receiving a TB skin test [PPD] during this assessment period
- The number of persons with active disease or with LTBI that are identified through targeted skin testing
- The number of persons placed on medication for active TB disease or LTBI treatment
- The number of persons completing treatment for TB disease or LTBI.

Agency _____
TB Control Official _____
Assessment Period ___/___/____ to ___/___/____

Action/Finding This Assessment Period	Number	QA	Comment
Total number of persons assessed this period	a		Include all persons with population risk factors assessed during this period. (Contact investigations, including those with administrative testing, are analyzed separately.)
Number of these persons with documented prior + PPD & without documentation of prior LTBI treatment completion	b		Treatment for LTBI is indicated if not previously completed. Ensure a medical evaluation; expect LTBI treatment orders unless contraindicated. (Persons under current treatment are evaluated on a one-to-one basis.)
Number of these persons with documented prior + PPD who have credible evidence of completing an approved LTBI treatment regimen	c		Look for documentation of a completed regimen. (Ensure a medical eval. when evidence is incomplete, in presence of any signs & symptoms, or for any other issue that indicates need for medical eval.)
Total persons receiving a PPD during this assessment period	d		Includes those for whom a PPD was placed, read and documented.
Number of persons identified as TB infected with newly positive PPDs	e	e ÷ d x 100= ___%	Rate of newly identified TB infection. Persons in c are handled on a one-to-one basis.
Number of persons with completed medical evaluations, determined to be free of active TB disease, but with a diagnosis of LTBI	f		All untreated persons with a + PPD should be medically evaluated. (Include past positives without evidence of treatment completion for LTBI and anyone with signs & symptoms of TB.)
Number of persons diagnosed with active TB disease and started on treatment (Also evaluate - Do 100 % of those diagnosed with active disease begin treatment and subsequently complete the regimen?)	g	g ÷ a x 100 = ____%	Persons who are suspected of infectious TB disease are isolated until disease and infectiousness are ruled out. When disease is diagnosed, isolation is maintained until noninfectious and a plan for treatment adherence is established.
Number of persons completing a full, approved regimen of therapy for active TB disease as a result of this assessment effort	h	h ÷ g x 100 = ____%	Public Health priority: ensure adherence to, and completion of, a full, approved regimen for active disease treatment *unless contraindicated* to protect the health of the public.
Number of persons started on LTBI treatment (The persons in b and e with no contraindications for LTBI treatment; emphasis on high priority candidates.)	i		A person with a +PPD needs to be referred for a CXR and medical evaluation. If active TB disease is ruled out, treatment for LTBI is expected, unless contraindicated. (Also evaluate the number of those diagnosed LTBI for whether or not they were started on LTBI treatment.)
Number of persons completing a full, approved regimen for LTBI treatment	j	j ÷ i x 100 = %	Target efforts toward achieving completion of an approved LTBI treatment regimen unless contraindicated.

* MMWR, June 9, 2000, Vol. 49, No. RR-6, pages 7-10.

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STATE OF WISCONSIN
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Sample TB Skin Test Analysis – Newly Hired Health Care Staff

Purpose - This form should be used to determine

- The number of employees screened for TB during this assessment period
- The number of employees with active disease or with LTBI identified through screening and TB skin tests [PPD]
- The number of employees started on medication for active TB disease or LTBI treatment
- The number of employees completing treatment for TB disease or LTBI treatment

Agency/Facility _____
TB Control Official _____
Assessment Period ___/___/____ to ___/___/____
No. of employees hired during period for whom screening is required _____ †

Action/Finding This Assessment Period	Number	QA	Comment
Total employees *screened*	a		QA : ***** All new employees requiring screening should be screened.
Number of employees with documented prior + PPD *with* verifiable completion of an approved LTBI treatment regimen.	b		Verify undocumented or questionable + PPD reports by applying a new PPD unless contraindicated by severe past reaction. [Persons with doc. of treatment completion should be re-evaluated periodically with vigilance for active disease on an individualized basis, depending upon their risk factors.]
Number of employees with documented prior + PPD *without* verifiable completion of an approved LTBI treatment regimen.	c		If no approved regimen for LTBI treatment has been completed, a medical evaluation is indicated. (Expect a CXR and LTBI treatment orders unless contraindicated.)
Number of newly hired employees receiving PPD skin testing	d		New employees who will be skin tested periodically: Two-step Mantoux test if no documented negative test in past 12 months. †
Number of newly hired employees with newly identified + PPD results.	e	(c + e) ÷ a x 100 = ____%	This is the rate of untreated new employees entering employment with TB disease or LTBI. (Includes untreated newly identified positives plus untreated past positives ÷ # of new emp. screened this period x 100.)
Number of + PPD employees referred for a medical evaluation	f		All employees with a documented + PPD who have *not completed a full regimen of treatment for LTBI* should be evaluated. (Expect a CXR to rule out active disease & prescription for LTBI treatment unless either is contraindicated/not indicated.)
Number referred who completed evaluation	g	g ÷ f x 100 = ____%	A medical evaluation should be completed for every employee for whom it is indicated. †
Number screened with active disease diagnosis	h	h ÷ a x 100 = ____%	Active disease rate for newly hired employees. (Diagnosis of active disease means employee must be medically evaluated to be noninfectious to be in work area with others.)
Number starting treatment for active disease	i	i ÷ h x 100 = ____ %	All persons with active disease need treatment to protect the health of the public. Contact Investigation required.
Number completing treatment for active disease	j	j ÷ h x 100 = ___%	All persons diagnosed with active disease who do not complete treatment are a risk to themselves & to the health of the public (also evaluate: j ÷ i x 100 = ___%)
Number of persons screened that were diagnosed as LTBI [k = c + (e – h)]	k	k ÷ a x 100 = ____ %	Pre-treatment LTBI rate, new emp. (Testing requires follow up evaluation and a commitment to treating those infected, unless contraindicated.)
Number starting LTBI treatment	l	l ÷ k x 100 = ____ %	Persons with LTBI should complete a treatment regimen unless contraindicated. (Treatment refused, not implemented or not completed creates a potential risk to the person and to the health of the public - Evaluate (m ÷ k) x 100 = _____%)
Number completing LTBI treatment	m	m ÷ l x 100 = ____ %	Persons starting treatment should complete an approved regimen unless contraindicated to avoid progression to active dis. and potential drug resistance

† Follow employer's licensing/certifying requirements as well as any OSHA , Department of Commerce, or other legal requirements.

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(608) 266-9692

Sample TB Skin Test Analysis – Continuing Health Care Staff

Purpose - This form should be used to determine

- The number of continuing employees screened for TB during this assessment period who have a TB skin test [PPD] conversion [Increase of 10mm in 2 yrs.]
- The number of employees with active disease or with LTBI identified through screening/skin testing
- The number of employees placed on medication for active TB disease or LTBI treatment & the number who complete therapy.

Agency/Facility _____
TB Control Official _____
Assessment Period ___/___/____ to ___/___/____
No. employees designated to receive screening this period___ †

Action/Finding This Assessment Period	Number	QA	Comments
Total employees screened	a		*All employees designated for screening/testing during the period should be screened or tested as appropriate.
Number of employees with documented prior + PPD *with* verifiable completion of an approved LTBI treatment regimen.	b		Verify undocumented or questionable + PPD reports by applying a new PPD unless contraindicated by severe past reaction. (Continuing employees with *documented* prior + PPD and *documentation* of a completed regimen can be screened for signs, symptoms & exposures; CXR and/or medical evaluation if indicated by findings, physician diagnosis or if required by employer.) †
Number of employees with documented prior + PPD *without* verifiable completion of an approved LTBI treatment reg.	c		**If no approved regimen for LTBI treatment has been completed, employee needs individualized on-going evaluation. (Physician or employer may order a CXR and/or sputum testing. Continue promoting LTBI treatment unless contraindicated, according to risk of active disease.) †
Number of continuing employees receiving PPD skin testing	d		Continuing employees who are periodically skin tested may have a single test if a two step was done upon hire and/or documented within 12 months. †
Number of continuing employees with *newly identified* + PPD results – These are the new converters.	e	e ÷ d x 100 = _____ %	This is the rate of continuing employees with newly identified LTBI infection. (Evaluate number of new converters for possible clusters [**2** or more in 3 mos. MMWR 10-28-94] who, when, where & with whom they had *close* contact, assess for poss. exposure/transmission from known/unknown source.).
Number of PPD + employees referred for a medical evaluation [Includes newly + PPD persons (converters) & any past + PPDs with a screening plan indicating med. eval.]	f		All employees with a documented + PPD who have *not completed a full regimen of treatment for LTBI* need individualized on-going screening. (Physician or employer may order a CXR &/or sputum tests to rule out active disease periodically or based upon sign & symptom screening. Continue promoting LTBI treatment unless contraindicated, according to risk of active disease.)
Number referred who completed evaluation	g	g ÷ f x 100 = _____ %	A medical evaluation should be completed for every employee for whom it is indicated. †
Number screened with an active disease diagnosis	h	h ÷ a x 100 = ___%	Active disease rate for continuing employees (Diagnosis of active disease means employee must be medically evaluated as noninfectious to be in work area with others.)
Number starting treatment for active disease	i	i ÷ h x 100 = _____ %	All persons with active disease need treatment to restore their health and to protect the health of the public. Contact investigation required.
Number completing treatment for active disease	j	j ÷ h x 100 = _____ %	All persons with active disease who do not complete treatment are a risk to themselves and to the health of the public. (Also evaluate: j ÷ i x 100 = ___% - do those starting also complete?)
Number screened with LTBI diagnosis [k = c + (e – h)]	k	k ÷ a x 100 = __%	Pre-treatment LTBI rate, continuing employees. (Testing requires follow up evaluation and a commitment to treating those who are infected, unless contraindicated.)
Number starting LTBI treatment	l	l ÷ k x 100 = _____ %	Persons with LTBI without documented treatment completion should receive medical treatment unless contraindicated. (Treatment refusal creates a potential for risk to the person and to the health of the public.)
Number completing LTBI treatment	m	(m ÷ l) x 100 =___%	Persons beginning treatment should complete an approved regimen unless contraindicated to avoid progression to active disease and potential drug resistance.

† Follow employer's licensing/certifying requirements as well as any OSHA, Department of Commerce, or other legal requirements.

Certificate of Participation

Awarded to

_____

For Participation in

Tuberculosis Skin Test Training Session

On _____

At _____

_____ _____

Date *Signature, Training Coordinator*

Certificate of Completion

Awarded to

_____

Mantoux Tuberculosis Skin Test Training

Presented by

_____ _____

Date *Signature*

_____

Location